

EXHIBIT B3

April Zambelli-Weiner, Ph.D.

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

-----X
IN RE JOHNSON & JOHNSON) MDL No.
TALCUM POWDER PRODUCTS) 16-2738 (FLW)(LHG)
MARKETING SALES PRACTICES,)
AND PRODUCTS LIABILITY)
LITIGATION)
)
THIS DOCUMENT RELATES TO)
ALL CASES)
-----X

V O L U M E I

VIDEOTAPED DEPOSITION OF
APRIL ZAMBELLI-WEINER, Ph.D.
WASHINGTON, D.C.
FRIDAY, JANUARY 11, 2019
8:59 A.M.

Pages: 1 - 209

Reported by: Leslie A. Todd

April Zambelli-Weiner, Ph.D.

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<p>1 Deposition of APRIL ZAMBELLI-WEINER, Ph.D., 2 held at the offices of: 3 4 5 ASHCRAFT & GEREL, LLP 6 1825 K Street, N.W. 7 Washington, DC 20005 8 9 10 11 12 Pursuant to notice, before Leslie Anne Todd, 13 Court Reporter and Notary Public in and for the 14 District of Columbia, who officiated in 15 administering the oath to the witness. 16 17 18 19 20 21 22 23 24 25</p>	<p>1 APPEARANCES (Continued): 2 3 ON BEHALF OF THE JOHNSON & JOHNSON DEFENDANTS: 4 MARK HEGARTY, ESQUIRE 5 SHOOK, HARDY & BACON, LLP 6 2555 Grand Boulevard 7 Kansas City, Missouri 64108 8 (816) 474-6550 9 10 GEOFFREY M. WYATT, ESQUIRE 11 SKADDEN, ARPS, SLATE, MEAGHER & FLOM, LLP 12 1440 New York Avenue, N.W. 13 Washington, D.C. 20005 14 (202) 371-7008 15 16 ON BEHALF OF THE PCPC: 17 THOMAS LOCKE, ESQUIRE 18 SEYFARTH SHAW LLP 19 975 F Street, NW 20 Washington, D.C. 20004 21 (202) 463-2400 22 23 24 25</p>
Page 3	Page 5
<p>1 A P P E A R A N C E S 2 ON BEHALF OF THE PLAINTIFFS: 3 CHRISTOPHER V. TISI, ESQUIRE 4 WESIEY BOWDEN, ESQUIRE 5 LEVIN PAPANTONIO THOMAS 6 MITCHELL RAFFERTY PROCTOR, P.A. 7 316 South Baylen Street 8 Pensacola, Florida 32502 9 (850) 435-7184 10 11 MICHELLE A. PARFITT, ESQUIRE 12 ASHCRAFT & GEREL, LLP 13 4900 Seminary Road, Suite 650 14 Alexandria, Virginia 22311 15 (703) 997-1774 16 17 DAVID J. STANOCH, ESQUIRE 18 GOLOMB & HONIK, PC 19 1835 Market Street 20 Suite 2900 21 Philadelphia, Pennsylvania 19103 22 (215) 278-4449 23 24 25</p>	<p>1 APPEARANCES (Continued): 2 3 ON BEHALF OF THE IMERY'S DEFENDANTS: 4 MARYAM M. MESEHA, ESQUIRE 5 COUGHLIN DUFFY, LLP 6 350 Mount Kemble Avenue 7 Morristown, New Jersey 07962 8 (973) 267-0058 9 10 MICHAEL R. KLATT, ESQUIRE 11 GORDON & REES SCULLY MANSUKHANI, LLP 12 816 Congress Avenue 13 Suite 1510 14 Austin, Texas 78701 15 16 ON BEHALF OF PTI: 17 MICHAEL ANDERTON, ESQUIRE 18 TUCKER ELLIS, LLP 19 950 Main Avenue 20 Suite 1100 21 Cleveland, Ohio 44113-7213 22 (216) 696-4835 23 24 ALSO PRESENT: 25 DANIEL HOLMSTOCK (Videographer)</p>

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<p>1 EXHIBITS</p> <p>2 (Attached to transcript)</p> <p>3 ZAMBELLI-WEINER DEPOSITION EXHIBITS PAGE</p> <p>4 No. 11 Article entitled "The role of</p> <p>5 epidemiology in the law: A toxic</p> <p>6 tort litigation case" 60</p> <p>7 No. 12 Letter to Samuel S. Epstein from</p> <p>8 Steven Musser (FDA), dated April 1,</p> <p>9 2014 173</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 DIRECT EXAMINATION</p> <p>2 BY MR. HEGARTY:</p> <p>3 Q Good morning, Doctor.</p> <p>4 A Good morning.</p> <p>5 Q My name is Mark Hegarty. I represent</p> <p>6 the Johnson & Johnson defendants in this case.</p> <p>7 Would you please state your full name</p> <p>8 for the record, please.</p> <p>9 A Sure. April Zambelli-Weiner.</p> <p>10 Q And, Doctor, who is your current</p> <p>11 employer?</p> <p>12 A My current employer is TTi Health</p> <p>13 Research and Economics.</p> <p>14 Q Where's that located?</p> <p>15 A Westminster, Maryland.</p> <p>16 Q Do you have a separate consulting</p> <p>17 business for litigation or is your litigation work</p> <p>18 also through TTi?</p> <p>19 A No separate consulting business.</p> <p>20 Q Where do the fees go that you earn as an</p> <p>21 expert witness?</p> <p>22 A They go to the company.</p> <p>23 Q Do any of those fees go directly to you?</p> <p>24 A No.</p> <p>25 Q Is your compensation at TTi in any way</p>

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<p>1 enhanced by the money you get paid in your 2 litigation work or in testifying in a case like 3 this?</p> <p>4 A Well, I -- I am the owner of TTi. It's 5 actually owned by a holding company that I own.</p> <p>6 Q So going back to my question --</p> <p>7 A Sure.</p> <p>8 Q -- as the owner of TTi and so owner of 9 the holding company, is your compensation for -- 10 for a year in any way affected by the amount of 11 litigation work that you do?</p> <p>12 A No.</p> <p>13 Q So whether you -- you bill zero in this 14 case or 100,000 in 2018, it would have no impact 15 on your compensation in 2018?</p> <p>16 A It would have no impact. It's also a 17 very small portion of what my company does, so in 18 that aspect it would also have no -- no tangible 19 impact.</p> <p>20 Q When you say it's a very small portion, 21 what do you mean?</p> <p>22 A Of our total revenue, litigation support 23 is under 10 percent.</p> <p>24 Q I had seen a reference in a prior 25 deposition that you had estimated that litigation</p>	<p>1 paying for your time?</p> <p>2 A Yes.</p> <p>3 Q And who did you -- who assisted you in 4 any way in working on this litigation?</p> <p>5 A Some research assistants and 6 epidemiologists.</p> <p>7 Q What are their names?</p> <p>8 A Ashley Sier.</p> <p>9 Q Who else?</p> <p>10 A Carter Little.</p> <p>11 Q Anyone else?</p> <p>12 A Those are the main two.</p> <p>13 Q What is Ashley Sier's area of expertise?</p> <p>14 A She's an epidemiologist.</p> <p>15 Q Is she also at TTi?</p> <p>16 A Yes.</p> <p>17 Q How about Carter Little, what is -- what 18 is his area?</p> <p>19 A Oh, it's a she.</p> <p>20 Q I'm sorry. She.</p> <p>21 A And she is a research assistant, so she 22 works across a lot of areas doing research 23 support.</p> <p>24 Q What did Ashley Sier do in connection 25 with your work on the case we're here to talk</p>
Page 11	Page 13
<p>1 work at TTi was 25 to 35 percent. Was that -- has 2 that changed or do you remember testifying to 3 that?</p> <p>4 A I don't remember testifying to that, but 5 it certainly has -- has changed and decreased.</p> <p>6 Q Approximately when did it start 7 decreasing?</p> <p>8 A It's hard to say. I haven't really done 9 any testifying work for several years, so it's a 10 very -- very small portion. I have some work that 11 is not testifying, but I would say it's been 12 substantially sort of steadily decreasing over 13 time.</p> <p>14 Q Do you have any other sources of income 15 except through your work at TTi?</p> <p>16 A No.</p> <p>17 Q What are you charging plaintiffs' 18 counsel in this case by the hour?</p> <p>19 A I believe it's 550 an hour. That's my 20 standard consulting rate.</p> <p>21 Q Did others help you that you charged 22 plaintiffs' counsel? In other words, did others 23 help you with your report or in any way assist you 24 in your work on this case that you event- -- you 25 ultimately charged the -- the attorneys who were</p>	<p>1 about?</p> <p>2 A She would have, under my direction, 3 pulled papers, run calculations, that type of 4 support activity.</p> <p>5 Q What did Carter Little do?</p> <p>6 A Probably similar.</p> <p>7 Q Did either Ms. Sier or Ms. Little help 8 you write your expert report in this case?</p> <p>9 A No.</p> <p>10 Q Did anyone at TTi assist you in writing 11 your expert report?</p> <p>12 A No.</p> <p>13 Q I'm going to mark as Exhibit No. 1 14 copies of the invoices that have been provided to 15 us today.</p> <p>16 (Zambelli-Weiner Exhibit No. 1 was 17 marked for identification.)</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q Would you look at Exhibit 1, Doctor, and 20 tell me what it is.</p> <p>21 A This looks like an invoice from 22 November.</p> <p>23 Q Well, let me ask you in more detail.</p> <p>24 A Mm-hmm.</p> <p>25 Q Are the invoices that are reflected in</p>

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<p style="text-align: right;">Page 14</p> <p>1 Exhibit No. 1 all the invoices that TTI has 2 generated for your work on this case? 3 MR. TISI: Well, I assume -- just, I 4 mean, I'm -- she spent some time recently -- I 5 don't know if her billing is up to date, but it is 6 accurate as of the last date of the last bill. 7 THE WITNESS: I'm just looking at the 8 dates. December, it looks like that covers -- 9 right, so there might be December or January time 10 that hasn't been billed yet. 11 BY MR. HEGARTY: 12 Q Do you have a sense for how much 13 additional time you have not billed that's not 14 reflected in Exhibit No. 1? 15 A I couldn't say for sure, but based on 16 when my report was submitted, I would say probably 17 not very much, probably just to prepare for today. 18 Q How much time did you spend preparing 19 for today? 20 A I'm not sure. 21 Q Can you give an estimate of less than 10 22 hours, less than 20 hours? 23 A More than 10. I don't know if it's more 24 than 20 or -- yeah. 25 Q Your best estimate of the amount of time</p>	<p style="text-align: right;">Page 16</p> <p>1 No. 1 been paid? 2 A We are current on payments, yes, to my 3 knowledge. 4 Q Now, we're here today to take your 5 deposition in the case of In Re: Johnson & 6 Johnson Talc Litigation MDL. You're aware that 7 you've been designated as a testifying expert in 8 that case? 9 A Correct. 10 Q When were you first contacted about 11 serving as an expert witness in this case? 12 A I'm not certain of that. 13 Q Was it in 2018? 14 A Yes, it was in 2018. 15 Q Your invoice, if you want to refer to 16 it, indicates that you first started working on 17 this matter in October. Does that look right? 18 A That looks correct. 19 Q Does that in any way refresh your memory 20 as to when you were first contacted about working 21 on this case? 22 A It would have been sometime in proximity 23 to that date. Yeah. 24 Q So sometime in the proximity of October 25 2018, you were contacted about -- of working on</p>
<p style="text-align: right;">Page 15</p> <p>1 spent preparing for today is more than 10? 2 A More than 10, yeah. 3 Q Are you -- was it less than 30? 4 A It was less than a full week, I would 5 say. I'm just -- I'm just estimating, so I'm just 6 going to caveat that with I'm not certain. 7 Q Will that preparation time be billed by 8 the hour? 9 A Yes. 10 Q Will that -- will that be billed at the 11 \$550 per hour rate? 12 A Correct. 13 Q Are the -- strike that. 14 Is the work of Ms. Sier and Ms. Little 15 reflected in the invoices that we marked as 16 Exhibit No. 1? 17 A It -- it should be, yes. 18 Q How is it reflected? 19 A In the other labor categories that 20 are -- that are listed. 21 Q Were you paid a retainer to work on this 22 matter? 23 A I -- it looks like it, but I don't do 24 the billing, so I'm -- I'm not certain. 25 Q Have all the invoices set out in Exhibit</p>	<p style="text-align: right;">Page 17</p> <p>1 this matter, correct? 2 A Sometime -- 3 MR. TISI: As an expert, that's correct. 4 BY MR. HEGARTY: 5 Q Who contacted you? 6 A I believe it was Chris. 7 Q Chris Tisi? 8 A Chris Tisi, yes. 9 Q Have you had any prior litigation work 10 with Ms. -- Mr. Tisi? 11 A I've never been a testifying expert for 12 Chris before. 13 Q Have you worked with him, though, in the 14 past? 15 A Yes. 16 Q In what matters have you worked with him 17 in the past? 18 MR. TISI: Objection. 19 You can answer that question. 20 THE WITNESS: GranuFlo. And I'm not 21 sure if there were any others. 22 BY MR. HEGARTY: 23 Q How long ago was the GranuFlo matter? 24 A It's been a while. Years. I don't 25 remember.</p>

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<p style="text-align: right;">Page 18</p> <p>1 Q Between the time you worked with</p> <p>2 Mr. Tisi on the GranuFlo litigation and the time</p> <p>3 you were contacted around October of 2018, had you</p> <p>4 had any other work with him where you were</p> <p>5 designated as a consulting expert?</p> <p>6 MR. TISI: A consult -- when you say</p> <p>7 "consulting expert," you --</p> <p>8 MR. HEGARTY: I'm sorry --</p> <p>9 MR. TISI: I just want to make sure</p> <p>10 she's clear about the distinction between</p> <p>11 consulting --</p> <p>12 MR. HEGARTY: Let me rephrase it.</p> <p>13 MR. TISI: -- and testifying expert.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q Between the time you worked with</p> <p>16 Mr. Tisi on the GranuFlo litigation and the time</p> <p>17 that you were contacted about testifying in this</p> <p>18 case, have you -- had you worked with Mr. Tisi</p> <p>19 where you were designated as an expert witness in</p> <p>20 the -- in a case?</p> <p>21 A No.</p> <p>22 Q Other than Mr. Tisi, had you worked in</p> <p>23 the past on litigation matters with any of the</p> <p>24 other lawyers you understand represent plaintiffs</p> <p>25 in this litigation?</p>	<p style="text-align: right;">Page 20</p> <p>1 MR. HEGARTY: That's fair.</p> <p>2 MR. TISI: Okay.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q Have you worked with Ms. Parfitt in any</p> <p>5 other matter where you were designated as a</p> <p>6 testifying expert besides the GranuFlo litigation?</p> <p>7 MR. TISI: Well, she was not a</p> <p>8 testifying expert in the GranuFlo litigation.</p> <p>9 THE WITNESS: I don't -- I'm sorry, can</p> <p>10 you repeat the question?</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q Sure.</p> <p>13 Have you worked with Ms. Parfitt in any</p> <p>14 other litigation where you were identified as a</p> <p>15 witness or a testifying expert?</p> <p>16 A Not that I can recall. I didn't work</p> <p>17 with her directly.</p> <p>18 Q Have you worked with any other lawyers</p> <p>19 in this room besides those we've talked about?</p> <p>20 A No, I don't believe so.</p> <p>21 Q What was your role in the GranuFlo</p> <p>22 litigation?</p> <p>23 A Just to consult on broad scientific,</p> <p>24 epidemiologic issues.</p> <p>25 MR. TISI: And that's all the questions</p>
<p style="text-align: right;">Page 19</p> <p>1 MR. TISI: Objection. Overbroad.</p> <p>2 THE WITNESS: I will say I don't know</p> <p>3 who all the lawyers are. There's a lot.</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q Let me ask it this way: Had you -- have</p> <p>6 you worked with any of the other lawyers in this</p> <p>7 room?</p> <p>8 A I've worked with Michelle before.</p> <p>9 Q That's Ms. Parfitt?</p> <p>10 A Yes.</p> <p>11 Q When have you worked --</p> <p>12 A Sorry.</p> <p>13 Q When have you worked with Ms. Parfitt?</p> <p>14 A Also on GranuFlo.</p> <p>15 Q Have you worked with her on any other</p> <p>16 litigations?</p> <p>17 A Not that I can recall.</p> <p>18 MR. TISI: Well, I just -- I just want</p> <p>19 to be clear. When you say "worked with her on any</p> <p>20 other litigations," are you talking about as a</p> <p>21 testifying expert or as a consultant?</p> <p>22 MR. HEGARTY: I assume you'll object if</p> <p>23 I just ask about consulting.</p> <p>24 MR. TISI: Yes, I will object on -- I</p> <p>25 allowed that one question on GranuFlo because --</p>	<p style="text-align: right;">Page 21</p> <p>1 I'll allow on that. Thank you.</p> <p>2 BY MR. HEGARTY:</p> <p>3 Q Was the contact that you had with</p> <p>4 Mr. Tisi via telephone call --</p> <p>5 MR. TISI: On this case?</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q -- for purposes of working on this case?</p> <p>8 A Mostly by telephone. I'm not sure if we</p> <p>9 met -- I think we might have met once or twice at</p> <p>10 a meeting. Not -- I'm getting confused.</p> <p>11 MR. TISI: Yes.</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q As of the time of the first call that</p> <p>14 you had with Mr. Tisi about working on this</p> <p>15 matter, were you retained at that first call?</p> <p>16 MR. TISI: Well, I'm going to object.</p> <p>17 When you say "on this matter," I assume you mean</p> <p>18 as a testifying expert.</p> <p>19 MR. HEGARTY: Yes.</p> <p>20 MR. TISI: Thank you.</p> <p>21 MR. HEGARTY: We'll start there.</p> <p>22 THE WITNESS: No, I don't believe so,</p> <p>23 no.</p> <p>24 BY MR. HEGARTY:</p> <p>25 Q Was there a time period before the --</p>

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<p style="text-align: right;">Page 22</p> <p>1 where you reviewed materials before you agreed to</p> <p>2 serve as a testifying expert in this case?</p> <p>3 A Yes.</p> <p>4 Q During that time from your perspective,</p> <p>5 were you retained as an expert in this case?</p> <p>6 MR. TISI: As a consulting -- as a</p> <p>7 consultant at that point, not as a testifying</p> <p>8 expert. And so no further questions on that will</p> <p>9 I permit.</p> <p>10 BY MR. HEGARTY:</p> <p>11 Q At what point in time from the initial</p> <p>12 phone call that you had with Mr. Tisi did you</p> <p>13 understand you were retained as a consulting</p> <p>14 expert?</p> <p>15 MR. TISI: Well, objection. Assumes</p> <p>16 facts not in evidence.</p> <p>17 Go ahead.</p> <p>18 THE WITNESS: I was retained as a</p> <p>19 consulting expert prior to having conversations</p> <p>20 about being a litigation -- like testifying</p> <p>21 expert.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q Were you retained as a consulting expert</p> <p>24 during the first call that you had with Mr. Tisi</p> <p>25 about this litigation?</p>	<p style="text-align: right;">Page 24</p> <p>1 an epidemiology, she -- epidemiologist, she</p> <p>2 understands all of the nuances of the questions</p> <p>3 you asked or -- so I figured I would make that</p> <p>4 representation.</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q Before Mr. Tisi contacted you about</p> <p>7 serving as a consulting expert in this litigation,</p> <p>8 did you know anything about the talc litigation?</p> <p>9 MR. TISI: Objection. I think you --</p> <p>10 can we go off the record? Because I think I may</p> <p>11 be able to help you with this answer. I -- I did</p> <p>12 not --</p> <p>13 THE REPORTER: Are you off --</p> <p>14 MR. TISI: Yeah, we can go off the</p> <p>15 record.</p> <p>16 THE VIDEOGRAPHER: The time is 9:15 a.m.</p> <p>17 We're going off the record.</p> <p>18 (A discussion was held off the record.)</p> <p>19 THE VIDEOGRAPHER: The time is 9:16</p> <p>20 a.m., and we're back on the record.</p> <p>21 BY MR. HEGARTY:</p> <p>22 Q Doctor, we had a short discussion off</p> <p>23 the record about your initial contact about</p> <p>24 serving as a consultant in the MDL litigation.</p> <p>25 Who was -- who did you have that initial</p>
<p style="text-align: right;">Page 23</p> <p>1 A I don't believe so. I think we had --</p> <p>2 we had conversations before I was retained at all.</p> <p>3 Q What were the conversations you had</p> <p>4 before you were retained in any aspect about</p> <p>5 serving as a consulting expert or testifying</p> <p>6 expert in this matter?</p> <p>7 MR. TISI: Well, let me just object</p> <p>8 because she has only been a consultant in -- to</p> <p>9 the extent she's been -- she was a consultant on</p> <p>10 issues, and then became a testifying expert,</p> <p>11 that's the only context in which we have had</p> <p>12 communications with her about talc -- the talc</p> <p>13 litigation. So there's no -- there was never a</p> <p>14 time where we spoke to her when she was -- about</p> <p>15 talc issues when she was not retained as a</p> <p>16 consultant or a litigation expert.</p> <p>17 MR. HEGARTY: Okay.</p> <p>18 MR. TISI: I mean if that helps you --</p> <p>19 MR. HEGARTY: Well, the reason I had</p> <p>20 followed up with that question was because she</p> <p>21 said that there was a time period before she</p> <p>22 understood she was a consulting expert between</p> <p>23 when you had the first call and --</p> <p>24 MR. TISI: I understand. I understand.</p> <p>25 You and I understand. I'm not so sure as a -- as</p>	<p style="text-align: right;">Page 25</p> <p>1 contact with?</p> <p>2 A So if I'm recalling correctly, because</p> <p>3 it's been a little bit, I think it was Steve</p> <p>4 Rotman at Hausfeld.</p> <p>5 Q Had you previously worked with him?</p> <p>6 A Yes.</p> <p>7 Q In what -- in what matters?</p> <p>8 A GranuFlo.</p> <p>9 Q Any others?</p> <p>10 A I don't believe so.</p> <p>11 Q So the first contact was with Steve</p> <p>12 Rodman or Rotman.</p> <p>13 A Rot- -- Rotman.</p> <p>14 Q How do you spell that?</p> <p>15 A R-O-T-M-A-N, I think.</p> <p>16 Q Who else besides Mr. Rotman have you</p> <p>17 spoken with as part of your work in this</p> <p>18 litigation for the plaintiffs?</p> <p>19 A Testifying work?</p> <p>20 Q Let me -- let me ask it a different way.</p> <p>21 Your -- your initial contact with was Mr. Rotman,</p> <p>22 correct?</p> <p>23 A Correct.</p> <p>24 Q What other lawyers representing the</p> <p>25 plaintiffs in the talc MDL litigation have you</p>

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<p style="text-align: right;">Page 26</p> <p>1 spoken with about your work on this case?</p> <p>2 A "This case" being my report and</p> <p>3 testifying today?</p> <p>4 Q Correct.</p> <p>5 MR. TISI: Well, when you say "this</p> <p>6 case" -- Mark, I'm not trying to get in the way, I</p> <p>7 promise you. When you say "this case," that</p> <p>8 implies the whole breadth of, you know,</p> <p>9 consultant, expert. She just answered the</p> <p>10 question as a result of her report. I think it's</p> <p>11 important that you be clear as to what you're</p> <p>12 talking about, a consultant versus testifying</p> <p>13 expert.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q Doctor, you've not been designated to</p> <p>16 testify as an expert in any other talc case to</p> <p>17 your knowledge; is that correct?</p> <p>18 A Can you repeat, please?</p> <p>19 Q Have you been -- to your knowledge, have</p> <p>20 you been designated to testify as an expert or a</p> <p>21 witness in any other talc case, besides the talc</p> <p>22 MDL case?</p> <p>23 A No.</p> <p>24 Q What other lawyers besides Mr. Rotman</p> <p>25 have you spoken with concerning your work on the</p>	<p style="text-align: right;">Page 28</p> <p>1 there were a bunch of lawyers?</p> <p>2 A Yes.</p> <p>3 Q When was that?</p> <p>4 MR. TISI: I'm going to tell her not to</p> <p>5 answer any further questions because that involves</p> <p>6 the consulting that she did with us. So you got</p> <p>7 that she was a consultant and who she consulted</p> <p>8 with, and no further questions.</p> <p>9 MR. KLATT: Chris, I think to clarify,</p> <p>10 Rule 26 says for a consulting expert, what's not</p> <p>11 discoverable is facts known or opinions held by</p> <p>12 the consultant, but I don't think that's what Mark</p> <p>13 is asking.</p> <p>14 MR. HEGARTY: My question was simply --</p> <p>15 MR. TISI: When it was?</p> <p>16 MR. HEGARTY: -- when was the meeting</p> <p>17 that you mentioned with these lawyers.</p> <p>18 MR. TISI: If you can recall, you can</p> <p>19 tell him what that is, but --</p> <p>20 THE WITNESS: Also I looked and saw Wes,</p> <p>21 and I spoke to him.</p> <p>22 MR. HEGARTY: Okay.</p> <p>23 THE WITNESS: I'm not sure. I just</p> <p>24 really wouldn't want to speculate.</p> <p>25 BY MR. HEGARTY:</p>
<p style="text-align: right;">Page 27</p> <p>1 talc MDL case?</p> <p>2 MR. TISI: Whether consultant or as --</p> <p>3 as an expert, as in testifying.</p> <p>4 MR. HEGARTY: In any respect.</p> <p>5 THE WITNESS: In any respect.</p> <p>6 MR. TISI: I just want to make sure</p> <p>7 you're clear on that. Go ahead.</p> <p>8 THE WITNESS: I'm trying to remember.</p> <p>9 There was one meeting with a lot of lawyers, so I</p> <p>10 don't know who they all are. But I -- I have</p> <p>11 spoken to Leigh. I have spoken to --</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q Leigh O'Dell?</p> <p>14 A Leigh O'Dell, yes. Sorry.</p> <p>15 Q Who else, who you can recall?</p> <p>16 A John Restaino. Maybe James Gotz. I</p> <p>17 don't remember the names of a lot of the other</p> <p>18 people.</p> <p>19 Q Mr. Tisi certainly?</p> <p>20 A Yes.</p> <p>21 MR. TISI: And Ms. Parfitt.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q Ms. Parfitt?</p> <p>24 A And, yes, Ms. Parfitt.</p> <p>25 Q When was this one meeting where you said</p>	<p style="text-align: right;">Page 29</p> <p>1 Q Sometime between October 2018 and today,</p> <p>2 correct?</p> <p>3 A It was before October.</p> <p>4 Q Before October 2018?</p> <p>5 A Correct.</p> <p>6 Q Where was the meeting?</p> <p>7 A At some law firm or -- somewhere in D.C.</p> <p>8 Q Okay. Before being contacted by</p> <p>9 Mr. Rotman about working on the talc MDL case,</p> <p>10 what were you -- what did you know about the talc</p> <p>11 litigation?</p> <p>12 MR. TISI: Objection. Assumes facts not</p> <p>13 in evidence.</p> <p>14 THE WITNESS: I -- based on my</p> <p>15 recollection, I just knew of its existence. And I</p> <p>16 probably had read some literature and -- and seen</p> <p>17 some -- some articles about it.</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q What literature had you read?</p> <p>20 A I don't know. Just I generally peruse</p> <p>21 the scientific literature and get alerts, so I may</p> <p>22 have seen articles.</p> <p>23 Q Sitting here today, do you recall any</p> <p>24 specific articles or literature that you reviewed</p> <p>25 before being contacted about serving as an expert</p>

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<p>1 in the talc MDL case?</p> <p>2 MR. TISI: Objection to the term</p> <p>3 "expert."</p> <p>4 THE WITNESS: I don't recall any</p> <p>5 specific articles, no.</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q Have you spoken to anyone -- to anyone</p> <p>8 about the talc litigation before being contacted</p> <p>9 by Mr. Rotman?</p> <p>10 A Anyone being just anyone?</p> <p>11 Q Correct.</p> <p>12 MR. TISI: I'm sorry, could you repeat</p> <p>13 the question? Oh, actually, I'll look. Go ahead.</p> <p>14 THE WITNESS: I would actually</p> <p>15 appreciate it if you could repeat the question.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q The question was, had you -- have you --</p> <p>18 had you spoken to anyone about the talc litigation</p> <p>19 before being contacted by Mr. Rotman?</p> <p>20 A So I -- I probably spoke internally</p> <p>21 maybe to some people about it at the company. And</p> <p>22 I also have a colleague, David Schwartz, who we</p> <p>23 had some conversations about -- about it.</p> <p>24 Q What -- what prompted the conversation</p> <p>25 with Mr. Schwartz about the talc litigation?</p>	<p>1 have spoken if there were articles or literature.</p> <p>2 Q Before being contacted by Mr. Rotman</p> <p>3 about working on the talc MDL, were you aware of</p> <p>4 any of the allegations where -- looked at any of</p> <p>5 the pleadings, looked at any of the -- the other</p> <p>6 materials that might have been filed in any other</p> <p>7 lawsuits?</p> <p>8 A Not that I can recall.</p> <p>9 Q But you were ultimately retained and</p> <p>10 asked to give expert opinions in the talc MDL</p> <p>11 case, correct?</p> <p>12 A Correct.</p> <p>13 Q The lawyers for the plaintiffs paid you</p> <p>14 to review materials and offer opinions, correct?</p> <p>15 A Correct.</p> <p>16 Q Those opinions were ultimately set out</p> <p>17 in your November 16, 2018 MDL report, correct?</p> <p>18 A Correct.</p> <p>19 Q How many hours did you spend reviewing</p> <p>20 materials in connection with your work on your MDL</p> <p>21 report?</p> <p>22 A I don't recall. I guess that would</p> <p>23 probably be reflected in the invoices.</p> <p>24 Q Can you look at the invoices and tell</p> <p>25 how much time you spent working on your MDL</p>
Page 31	Page 33
<p>1 A He was interested in it, and he was</p> <p>2 interested in my expertise in genetic</p> <p>3 epidemiology.</p> <p>4 MR. TISI: I just -- I don't know who</p> <p>5 Mr. Schwartz is. Let me caution you if -- is</p> <p>6 Mr. Schwartz a lawyer and was consulting you in</p> <p>7 the context of --</p> <p>8 THE WITNESS: He's not a lawyer, no.</p> <p>9 MR. TISI: Okay.</p> <p>10 BY MR. HEGARTY:</p> <p>11 Q Has Mr. Schwartz --</p> <p>12 A But I -- but I do need to be careful. I</p> <p>13 do have a confidentiality agreement with him.</p> <p>14 Q Is Mr. Schwartz with TTI?</p> <p>15 A No.</p> <p>16 Q Who is he with?</p> <p>17 A He is with ISS, Innovative Science</p> <p>18 Solutions.</p> <p>19 Q Besides Mr. Schwartz, who else did you</p> <p>20 speak with about the talc litigation before being</p> <p>21 contacted by Mr. Rotman?</p> <p>22 A No one that I can think of.</p> <p>23 Q You said you spoke internally to folks</p> <p>24 at TTI. Who did you speak with internally?</p> <p>25 A I'm really just speculating that we may</p>	<p>1 report?</p> <p>2 A Not specifically working on the report,</p> <p>3 from the invoices.</p> <p>4 Q Are you able to estimate in any way</p> <p>5 today the amount of -- the number of hours you</p> <p>6 spent working on your MDL report?</p> <p>7 A No.</p> <p>8 Q Was it more than a week's worth, more</p> <p>9 than 40 hours?</p> <p>10 A I don't know.</p> <p>11 Q But whatever work you spent working on</p> <p>12 your MDL report would be reflected in the invoices</p> <p>13 we marked as Exhibit No. 1?</p> <p>14 A Correct, except for if there's -- I</p> <p>15 don't think there would be any outstanding</p> <p>16 invoices for that given the submission date, but</p> <p>17 just noting there are still possibly outstanding</p> <p>18 invoices.</p> <p>19 Q Are you able to estimate how many hours</p> <p>20 you spent talking with plaintiffs' counsel in</p> <p>21 connection with preparation of your report?</p> <p>22 A No.</p> <p>23 Q Are you able to estimate how many hours</p> <p>24 you spent talking with plaintiffs' counsel about</p> <p>25 your work on the MDL litigation in total, whether</p>

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<p style="text-align: right;">Page 34</p> <p>1 it's your report or otherwise?</p> <p>2 A No.</p> <p>3 Q Did you meet with lawyers for the</p> <p>4 plaintiffs yesterday?</p> <p>5 A Yes.</p> <p>6 Q How much time did you spend with them</p> <p>7 yesterday?</p> <p>8 A Maybe six hours-ish.</p> <p>9 Q Other than the initial -- strike that.</p> <p>10 Other than Mr. -- or Ms. Sier and</p> <p>11 Ms. Little, did you speak with any of your other</p> <p>12 colleagues at TTi about your work on the talc MDL</p> <p>13 case?</p> <p>14 A Just my husband.</p> <p>15 Q Does he work there as well?</p> <p>16 A He does.</p> <p>17 Q Did he assist you in any way in</p> <p>18 preparing your MDL report?</p> <p>19 A No.</p> <p>20 Q Has he assisted you in any way in the</p> <p>21 work you've done in the talc MDL that we're here</p> <p>22 to talk about today?</p> <p>23 A No.</p> <p>24 Q Have you discussed the MDL litigation</p> <p>25 case or your report with any of the other experts</p>	<p style="text-align: right;">Page 36</p> <p>1 information that we would have gotten with respect</p> <p>2 to a consulting witness.</p> <p>3 MR. LOCKE: Yeah, I disagree.</p> <p>4 MR. TISI: Okay. Take --</p> <p>5 MR. LOCKE: And I object and want it</p> <p>6 noted.</p> <p>7 MR. TISI: Take it up if you wish.</p> <p>8 MR. LOCKE: And reserve the right to</p> <p>9 continue the deposition.</p> <p>10 MR. TISI: I would obviously object to</p> <p>11 that, but as you wish.</p> <p>12 (Zambelli-Weiner Exhibit No. 2 was</p> <p>13 marked for identification.)</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q Doctor, I'm going to show you what I</p> <p>16 marked as Exhibit No. 2. This is a copy of your</p> <p>17 notice of deposition for today.</p> <p>18 Can you tell me whether you've seen</p> <p>19 Exhibit No. 2 before right now?</p> <p>20 A Yes, I have.</p> <p>21 Q On page -- beginning on page 3 and</p> <p>22 carrying over to pages -- page 8, there is a list</p> <p>23 of documents that we asked to be produced.</p> <p>24 Have you reviewed the paragraphs on</p> <p>25 pages 3 through 8 before right now?</p>
<p style="text-align: right;">Page 35</p> <p>1 that have been designated by the plaintiffs in the</p> <p>2 MDL?</p> <p>3 A No, I haven't.</p> <p>4 MR. TISI: Objection.</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q Have you reviewed any of the other</p> <p>7 plaintiffs -- plaintiff experts' MDL reports?</p> <p>8 MR. TISI: Objection.</p> <p>9 THE WITNESS: I am not certain, but I</p> <p>10 don't think so.</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q Did you ever review any draft reports</p> <p>13 from any of the plaintiffs' MDL experts?</p> <p>14 MR. TISI: Objection.</p> <p>15 To the extent that was there anything --</p> <p>16 he's asking for anything that came -- in the</p> <p>17 context with any consulting that we did. My -- I</p> <p>18 instruct you not to answer that question.</p> <p>19 THE WITNESS: Okay.</p> <p>20 MR. HEGARTY: Well, I don't think if she</p> <p>21 reviewed a draft MDL report from any of the other</p> <p>22 experts, that would be covered by confidentiality.</p> <p>23 MR. TISI: I think -- I think it is --</p> <p>24 it would be as a consult- -- it would be as a</p> <p>25 consultant. You're not entitled to consulting</p>	<p style="text-align: right;">Page 37</p> <p>1 A Yes, I have.</p> <p>2 MR. TISI: And I assume you got our</p> <p>3 objections as well, right, Mark?</p> <p>4 MR. HEGARTY: Yes.</p> <p>5 MR. TISI: Thank you.</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q Did you bring any materials with you</p> <p>8 here today in response to your deposition notice</p> <p>9 marked as Exhibit No. 2?</p> <p>10 A Excuse me. Yes, I did.</p> <p>11 Q What did you bring?</p> <p>12 A I brought an updated CV. I brought the</p> <p>13 invoices. I brought a USB drive with the articles</p> <p>14 and documents that are listed in my report. I</p> <p>15 also have a binder that has my copy of my report</p> <p>16 and some copies of other key documents and -- and</p> <p>17 notes.</p> <p>18 Q Did you bring anything else besides the</p> <p>19 materials you just mentioned?</p> <p>20 A Let me take a look and make sure I'm not</p> <p>21 forgetting anything. (Peruses document.)</p> <p>22 I -- I think that's it.</p> <p>23 MR. TISI: Mark, as I mentioned, I think</p> <p>24 this was outside the scope, but they were arguably</p> <p>25 outside the scope, and I brought two documents</p>

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<p style="text-align: right;">Page 38</p> <p>1 that I can't seem to put my hand on, but I just --</p> <p>2 I will give those to you. Those are e-mails</p> <p>3 related to -- yeah. If you want them now or we'll</p> <p>4 get them later, that's fine.</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q You mentioned that you brought the</p> <p>7 invoices we marked as Exhibit No. 1, correct?</p> <p>8 A Mm-hmm. Correct.</p> <p>9 Q I also was provided before the</p> <p>10 deposition started with a copy of your CV, which</p> <p>11 I'm marking as Exhibit No. 3.</p> <p>12 (Zambelli-Weiner Exhibit No. 3 was</p> <p>13 marked for identification.)</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q Would you look at Exhibit No. 3, and</p> <p>16 tell me whether that is the updated CV that you</p> <p>17 provided pursuant to your deposition notice.</p> <p>18 A Yes, I believe so.</p> <p>19 Q You also mentioned that you brought a</p> <p>20 USB drive. Do you have that with you?</p> <p>21 A I do.</p> <p>22 Q I'm marking as Exhibit 4 the USB drive</p> <p>23 that you handed me.</p> <p>24 (Zambelli-Weiner Exhibit No. 4 was</p> <p>25 marked for identification.)</p>	<p style="text-align: right;">Page 40</p> <p>1 MR. TISI: Just let me make sure we're</p> <p>2 not giving you two of the same -- wait a second.</p> <p>3 Okay. I got them both.</p> <p>4 And just to be clear, she brought them,</p> <p>5 but they were not -- we did not consider them</p> <p>6 responsive, but we brought them anyway, because we</p> <p>7 assumed you would be asking questions and then</p> <p>8 say, We'd like to have a copy.</p> <p>9 (Zambelli-Weiner Exhibit Nos. 6</p> <p>10 and 7 were marked for</p> <p>11 identification.)</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q Doctor, counsel provided me with copies</p> <p>14 of what I've marked as Exhibit Nos. 6 and 7.</p> <p>15 Would you please tell -- tell me what</p> <p>16 Exhibit No. 6 and Exhibit No. 7 are.</p> <p>17 A Number -- Exhibit No. 6 is an e-mail on</p> <p>18 behalf of my company to the European Journal of</p> <p>19 Cancer Prevention regarding their process for</p> <p>20 notifying them of issues with a paper that has</p> <p>21 been published.</p> <p>22 Q What is Exhibit No. 7?</p> <p>23 A Exhibit No. 7 is the same for the</p> <p>24 journal Anti-Cancer Research.</p> <p>25 Q Do you have any -- did you have any</p>
<p style="text-align: right;">Page 39</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q And, Doctor, again, tell me what's on</p> <p>3 the USB drive that we marked as Exhibit No. 4.</p> <p>4 A The articles and documents that are</p> <p>5 listed in my report.</p> <p>6 Q You also mentioned that you brought with</p> <p>7 you a binder of copies of your report and what you</p> <p>8 characterize as other key documents and notes. Do</p> <p>9 you have that with you?</p> <p>10 A I do.</p> <p>11 Q May I see it, please.</p> <p>12 A Mm-hmm, sure.</p> <p>13 Q Thank you.</p> <p>14 I'm going to mark as Exhibit No. 5 a</p> <p>15 copy of the notebook that you brought with you</p> <p>16 here today.</p> <p>17 (Zambelli-Weiner Exhibit No. 5 was</p> <p>18 marked for identification.)</p> <p>19 BY MR. HEGARTY:</p> <p>20 Q And how did you go about selecting the</p> <p>21 key documents you mentioned outside of your</p> <p>22 report?</p> <p>23 A Just what I felt was helpful for my</p> <p>24 prep.</p> <p>25 MR. HEGARTY: May I have those e-mails?</p>	<p style="text-align: right;">Page 41</p> <p>1 other correspondence via e-mail or otherwise with</p> <p>2 any other journals as part of your work on the</p> <p>3 talc MDL case?</p> <p>4 A No.</p> <p>5 Q Did you communicate by e-mail or</p> <p>6 otherwise with anyone else about your work on the</p> <p>7 talc MDL besides attorneys for the plaintiff?</p> <p>8 A No.</p> <p>9 Q In the -- in your report, you did a</p> <p>10 couple of fixed-effect analyses of the data from</p> <p>11 the 2003 Huncharek paper and the 2007 Huncharek</p> <p>12 and Muscat paper, correct?</p> <p>13 A Correct.</p> <p>14 Q There would have been calculations,</p> <p>15 data, et cetera, generated or -- to prepare the</p> <p>16 numbers that you put in the table, correct?</p> <p>17 A Not necessarily.</p> <p>18 Q Well, what did you do to prepare to put</p> <p>19 the -- to provide the numbers in the fixed effects</p> <p>20 -- for the fixed-effect models that you ran?</p> <p>21 A Sure. We ran the calculations and just</p> <p>22 transported the results into the table.</p> <p>23 Q Do those calculations still exist</p> <p>24 somewhere?</p> <p>25 A No.</p>

<p style="text-align: right;">Page 42</p> <p>1 Q Were they run via some sort of computer 2 program? 3 A Yes. 4 Q Is there a name for it? 5 A Stata. 6 Q Are there any written materials or 7 documents that you prepared as part of running 8 that fixed-effect -- fixed-effects analysis that 9 still exists? 10 A Not to my knowledge. 11 Q Did you develop any kind of protocol 12 before you ran that fixed-effects model test for 13 the two papers? 14 A It doesn't require a protocol. It's 15 just a calculation, trying to replicate their 16 calculation. 17 Q Did you do that calculation yourself or 18 did someone else do it? 19 A I had Ashley do it, and I reviewed it. 20 Q I'm going to mark as Exhibit No. 8 a 21 copy of the MDL report of yours that we've been 22 provided in this case. 23 (Zambelli-Weiner Exhibit No. 8 was 24 marked for identification.) 25 BY MR. HEGARTY:</p>	<p style="text-align: right;">Page 44</p> <p>1 Q Do you agree that you signed this 2 report, correct? 3 A That's correct. 4 Q And you signed this report with the same 5 intent as if signed under penalty of perjury, 6 correct? 7 A Correct. 8 Q And it's entitled to the same weight, 9 correct? 10 A Same weight as? 11 Q As if you signed that document under 12 penalty of perjury. 13 A Sure. 14 Q And it should be entitled to the same 15 weight as you would entitle a -- an article you 16 have had published in a journal, correct? 17 MR. TISI: Let me just object to the 18 question about perjury. I don't see where that 19 has any -- I'll just object. 20 Go ahead. 21 THE WITNESS: Can you rephrase that 22 question? 23 BY MR. HEGARTY: 24 Q Sure. 25 Your report should be entitled to the</p>
<p style="text-align: right;">Page 43</p> <p>1 Q Would you look at Exhibit No. 8 and tell 2 me whether that is your MDL report. 3 A I don't have a lot of room here. Sorry. 4 Yes, it is. Appears to be. 5 Q Does the notebook that we marked contain 6 an identical report to Exhibit No. 8? 7 A I believe it just has a different cover 8 page, but, otherwise, it should be identical. 9 Q Why is the cover page different? 10 A I'm guessing this is my version that I 11 submitted to the lawyers, and this is some legal 12 cover page that got put on it. 13 Q Other than the cover page, from what you 14 can tell, is the report and the notebook the same 15 as the report we marked as Exhibit No. 8? 16 A It should be. Has the same date on it. 17 Q The report we marked as Exhibit No. 8 18 defines the scope of your testimony in this 19 matter, correct? 20 A That's correct. 21 Q Is it correct that you prepared your 22 report with the same rigor and approach as you 23 would prepare an article for publication in a 24 journal? 25 A Yes.</p>	<p style="text-align: right;">Page 45</p> <p>1 same weight as you would entitle a -- an article 2 you publish in a journal, correct? 3 MR. TISI: Objection. 4 THE WITNESS: I'm not sure what you mean 5 by "weight." Perhaps you could rephrase that. 6 BY MR. HEGARTY: 7 Q Well, did you prepare the -- your report 8 in any way different than you would prepare an 9 article -- when you have prepared articles for 10 publication? 11 A Well, certainly, the -- the end 12 deliverable is different, but in terms of the 13 methods, the rigor, there would be no difference. 14 Q Your report is supposed to be your 15 testimony as if you're on the stand before a judge 16 and a jury. Do you understand that? 17 MR. TISI: Objection. 18 THE WITNESS: Yes, I do. 19 BY MR. HEGARTY: 20 Q Are there any necessary changes or 21 revisions to your report -- 22 A There is -- 23 Q -- as you -- that you know of sitting 24 here today? 25 A That I know of sitting here today, there</p>

<p style="text-align: right;">Page 46</p> <p>1 is one. Let me see if I can find it here. 2 (Peruses document.) 3 On page 30, there was a rounding error. 4 Q Where on page 30? 5 A So on -- at Booth, 1989, the lower limit 6 of the confidence interval under "Calculated OR" 7 should be 0.47. 8 Q Was that an error on your part? 9 A Yes. 10 Q Any other necessary changes or revisions 11 to your report? 12 A Not as I sit here today. 13 Q How did you catch that error? 14 A Just going back and rereviewing. 15 Q The opinions that you intend to offer in 16 this case are set out in your report, correct? 17 A Correct. 18 Q Now, as your report shows, you don't 19 intend to offer the opinion that use of Johnson's 20 baby powder or Shower to Shower causes ovarian 21 cancer, correct? 22 A That's correct. 23 Q And as your report shows, you don't -- 24 don't intent -- you did not do a risk assessment 25 or Bradford Hill analysis of all the literature</p>	<p style="text-align: right;">Page 48</p> <p>1 before? 2 A Sure. Everyone does. 3 Q You've made typographical errors, 4 correct? 5 A Correct. 6 Q You're misreported data or figures, 7 correct? 8 A I don't know about -- 9 MS. PARFITT: Objection. 10 THE WITNESS: -- the term "misreported," 11 but I certainly can -- can, you know, agree that 12 there could be errors in reporting of -- of 13 numbers. 14 BY MR. HEGARTY: 15 Q Have you miscited authorities in the 16 past? 17 MR. TISI: Objection. 18 THE WITNESS: Can you clarify that? 19 BY MR. HEGARTY: 20 Q Sure. Have you cited to authorities 21 that either were mixed up, in the wrong place, had 22 misspellings, had -- had wrong years of 23 publication? Have you done things like that? 24 A I'm sure, yes. 25 MR. TISI: Objection.</p>
<p style="text-align: right;">Page 47</p> <p>1 looking at talcum powder products and ovarian 2 cancer, correct? 3 A That's correct. 4 Q Along these same lines, the materials on 5 which you intend to rely on for purposes of your 6 opinions are identified in your report, correct? 7 A Correct. 8 Q Your report focuses on some of the work 9 of Drs. Huncharek and Muscat. Have you ever met 10 either of those doctors? 11 A I have not. 12 Q Have you ever spoken to either 13 Dr. Huncharek or Dr. Muscat? 14 A I have not. 15 Q Have you read any of their published 16 works besides those referenced in your report? 17 A I couldn't say for certain. 18 Q Sitting here today, do you know of any 19 other -- any other published works that you have 20 read besides those referenced in your report? 21 A I couldn't point to a specific 22 publication, no. 23 Q You just pointed out an error that you 24 made in your report. I assume that you agree that 25 you had made errors or mistakes in written work</p>	<p style="text-align: right;">Page 49</p> <p>1 BY MR. HEGARTY: 2 Q Have you ever failed to properly quote 3 material? 4 MR. TISI: Objection. 5 BY MR. HEGARTY: 6 Q And cite proper authorities for 7 quotations? 8 A It's possible. 9 Q Have you ever copied text from an 10 authority word for word and failed to properly 11 quote or cite the text? 12 MR. TISI: Objection. 13 THE WITNESS: Not to my knowledge, and 14 certainly not by intent. 15 BY MR. HEGARTY: 16 Q It would be wrong to do so, correct? 17 A Correct. 18 MR. TISI: Objection. 19 BY MR. HEGARTY: 20 Q And it would violate well-established 21 scientific guidelines for written work, correct? 22 MR. TISI: Objection. 23 THE WITNESS: What would? 24 BY MR. HEGARTY: 25 Q If an author copied text from an</p>

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<p style="text-align: right;">Page 50</p> <p>1 authority word for word and failed to properly 2 quote or cite the authority, that would violate 3 well-established scientific guidelines for written 4 work, correct? 5 MS. PARFITT: Objection. 6 THE WITNESS: I think that -- 7 MR. LOCKE: Can I -- can I just ask, are 8 you both representing the same people, right? 9 MS. PARFITT: We are. 10 MR. LOCKE: Do we need to have two 11 objections? 12 MR. TISI: Yeah, I'll -- 13 MS. PARFITT: But just in case -- 14 MR. TISI: I'm objecting. 15 MS. PARFITT: We're trying to keep the 16 stereo part of it down. 17 MR. HEGARTY: Yeah, I would prefer that 18 we have one person. 19 MR. LOCKE: Yeah, it just seems like if 20 we could have one counsel for plaintiffs. 21 MR. TISI: Well, while we're at it, I 22 just want to make sure, I believe -- I'm looking 23 at her documents considered, and I believe she was 24 provided with Dr. Muscat's deposition, and I'm not 25 seeing it here. I'm not saying it's not here, but</p>	<p style="text-align: right;">Page 52</p> <p>1 of, you know, an error, an oversight. 2 BY MR. HEGARTY: 3 Q Would it raise questions about the 4 quality of the author's work? 5 MR. TISI: Objection. 6 THE WITNESS: I would have to evaluate 7 that within the totality of the work itself. 8 BY MR. HEGARTY: 9 Q It certainly would be something that you 10 would -- you would not agree with that that should 11 -- that that is okay to do, correct? 12 MR. TISI: Objection. 13 THE WITNESS: Sure. I think everyone 14 seeks to have proper attribution, but I'm sure 15 errors and omissions happen. 16 BY MR. HEGARTY: 17 Q But you -- I think you've said in the 18 past that the vast majority of publications 19 contain errors of some kind, correct? 20 A I think I may have said that, but, sure, 21 errors happen. 22 Q That's true, the vast majority of 23 publications contain errors of some kind, correct? 24 MR. TISI: Objection. 25 THE WITNESS: Again, I can't say that</p>
<p style="text-align: right;">Page 51</p> <p>1 I just want to make sure. I believe that she was 2 provided with that. You may want to double-check 3 that. 4 BY MR. HEGARTY: 5 Q Let's go back to my question. 6 MR. TISI: Actually, it's here. Never 7 mind. It's on there. 8 BY MR. HEGARTY: 9 Q If an author copied text from an 10 authority word for word and failed to properly 11 quote or cite the authority, that would violate 12 well-established scientific guidelines for written 13 work, correct? 14 MR. TISI: Objection. 15 THE WITNESS: I think -- I think I would 16 generally agree with that. I think it would be 17 contextually dependent to some extent. 18 BY MR. HEGARTY: 19 Q If an author copied text from an 20 authority word for word and failed to properly 21 quote or cite the text, that would call into 22 question the scholarship of the author, correct? 23 MR. TISI: Objection. 24 THE WITNESS: Not necessarily. I 25 would -- I would put that potentially in the realm</p>	<p style="text-align: right;">Page 53</p> <p>1 with certainty, but I would say that I could agree 2 that that's probably true. 3 BY MR. HEGARTY: 4 Q Do you have your CV with you? 5 A Yep. 6 Q Now, I'm going to mark as Exhibit No. 9 7 the CV that you provided as part of your expert 8 report in pages 53 through 63 of your report. 9 (Zambelli-Weiner Exhibit No. 9 was 10 marked for identification.) 11 BY MR. HEGARTY: 12 Q And can you tell me, what changes have 13 been made between Exhibit 9 and your updated CV? 14 A I'm not certain. 15 Do you want me to sit here and look 16 through it? 17 Q Not page for page, and I will -- I will 18 make sure on the record that I'm not asking you to 19 do that. 20 Just from what you understand, without 21 looking through it, are you able to identify any 22 changes that you made between when we were 23 provided your report back in November of 2016 and 24 the one you provided today? 25 A I'm not sure what changes were made.</p>

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<p style="text-align: right;">Page 54</p> <p>1 Q Are there any errors in your current CV</p> <p>2 that we marked as exhibit -- what's that exhibit?</p> <p>3 A Oh, I'm sorry. I don't know which one</p> <p>4 is --</p> <p>5 MR. TISI: Exhibit --</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q Exhibit 3.</p> <p>8 A Is it -- this the new one?</p> <p>9 Q Are there any errors in Exhibit No. 3 of</p> <p>10 which you are aware?</p> <p>11 A Is Exhibit No. 3 the new one?</p> <p>12 Q Correct.</p> <p>13 A Not as I sit here.</p> <p>14 Do you want me to look through it?</p> <p>15 Q Well, let me ask you about a couple</p> <p>16 parts of your CV.</p> <p>17 I'm going to mark as Exhibit No. 10 a</p> <p>18 copy of the CV that you included as part of the</p> <p>19 report you prepared in the Accutane litigation.</p> <p>20 (Zambelli-Weiner Exhibit No. 10</p> <p>21 was marked for identification.)</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q I assume you've seen this before,</p> <p>24 correct?</p> <p>25 MR. TISI: I'm sorry, which -- you're</p>	<p style="text-align: right;">Page 56</p> <p>1 report that you prepared?</p> <p>2 A Yes.</p> <p>3 Q If you look under the "Positions Held"</p> <p>4 part of the Accutane CV as compared to your</p> <p>5 current CV, in the Accutane -- in the CV we marked</p> <p>6 as No. 10, you say from 2003 to 2010 you were a</p> <p>7 senior scientist and chief operating officer,</p> <p>8 Epidemiology International Inc.</p> <p>9 In your current CV, you say you were a</p> <p>10 principal epidemiologist, correct?</p> <p>11 A Correct.</p> <p>12 Q Did your title change between the CV</p> <p>13 that we marked Exhibit No. 10 and the CV that we</p> <p>14 marked Exhibit No. 3?</p> <p>15 A They're all true.</p> <p>16 Q Well, which title did you have?</p> <p>17 A All of them.</p> <p>18 Q Why did you choose in Exhibit No. 10 to</p> <p>19 list your title as senior scientist and chief</p> <p>20 operating officer versus the title that you list</p> <p>21 as principal epidemiologist now?</p> <p>22 A I don't know. I have a lot of versions</p> <p>23 of CVs. CVs undergo revisions for various</p> <p>24 reasons.</p> <p>25 Q So is it your testimony that you were a</p>
<p style="text-align: right;">Page 55</p> <p>1 going -- moving fast. Is this Exhibit No. 10?</p> <p>2 MR. HEGARTY: Yes.</p> <p>3 MR. TISI: Do we have 9? I have 8.</p> <p>4 MR. HEGARTY: Wasn't it 9 that --</p> <p>5 MS. PARFITT: It's the CV --</p> <p>6 MR. WYATT: It's the CV in her expert</p> <p>7 report.</p> <p>8 MR. TISI: Oh, I didn't know we marked</p> <p>9 it. Okay.</p> <p>10 THE WITNESS: So 10 is from Accutane?</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q Yes. You were -- you provided an expert</p> <p>13 report in the Accutane litigation, correct?</p> <p>14 A I did.</p> <p>15 Q And Exhibit No. 10 is the copy of the CV</p> <p>16 that you included as part of your expert report in</p> <p>17 the Accutane litigation, correct?</p> <p>18 A Well, I'll have to take your word for</p> <p>19 it. There's no designation.</p> <p>20 Q Well, in the upper right-hand corner, it</p> <p>21 says "Expert Report of Dr. April Zambelli-Weiner,"</p> <p>22 correct?</p> <p>23 A Correct. That doesn't necessarily tell</p> <p>24 me it's from Accutane.</p> <p>25 Q Does it tell you it was from an expert</p>	<p style="text-align: right;">Page 57</p> <p>1 senior scientist, chief operating officer and</p> <p>2 principal epidemiologist at Epidemiology</p> <p>3 International?</p> <p>4 A That's correct.</p> <p>5 Q And so you worked -- your CV says you</p> <p>6 worked at Epidemiology International from 2003 to</p> <p>7 2011. Was that the title of the company the</p> <p>8 entire time?</p> <p>9 A I believe, though, but -- it could have</p> <p>10 changed.</p> <p>11 Q Was it ever known as RidgeCom?</p> <p>12 A I believe that was her old company.</p> <p>13 Q Did you ever work for RidgeCom?</p> <p>14 A I may have received paychecks from</p> <p>15 RidgeCom. I don't know what their structure was.</p> <p>16 Q Do you list RidgeCom anywhere on your</p> <p>17 CV?</p> <p>18 A No.</p> <p>19 Q Did you ever work for a company called</p> <p>20 Sterilex Corp.?</p> <p>21 A I did work for Sterilex. Sterilex was</p> <p>22 owned by the same person who owned EI, and so I</p> <p>23 technically worked for EI but also did some work</p> <p>24 for Sterilex.</p> <p>25 Q Do you list your work at Sterilex in</p>

<p style="text-align: right;">Page 58</p> <p>1 your CV?</p> <p>2 MR. TISI: Objection.</p> <p>3 THE WITNESS: No.</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q And why not?</p> <p>6 A To me it's the same place.</p> <p>7 Q In your current CV, you tell the world</p> <p>8 that you were a research assistant at Wash U,</p> <p>9 correct?</p> <p>10 A Correct.</p> <p>11 Q In the CV we marked as Exhibit No. 10,</p> <p>12 you characterized your position as laboratory</p> <p>13 technician, correct?</p> <p>14 A Correct.</p> <p>15 Q Did your, again, position or title</p> <p>16 change between Exhibit No. 10 CV and your current</p> <p>17 CV?</p> <p>18 A Again, same answer: Both true.</p> <p>19 Q So your -- why the difference in title?</p> <p>20 A Again, I don't know. Maybe the CV was</p> <p>21 changed for a particular grant application or --</p> <p>22 or something. I'm just guessing.</p> <p>23 Q If you look over on page 57 of your CV,</p> <p>24 that's 57 of 63, that's Exhibit No. 9, you list a</p> <p>25 paper titled "Risk of neuroblastic associated</p>	<p style="text-align: right;">Page 60</p> <p>1 Q I'm going to mark as Exhibit No. 11 a</p> <p>2 copy of the paper whose citation is at the</p> <p>3 reference you note "Law, Probability and Risk,</p> <p>4 2008, 7, 15 to 34."</p> <p>5 (Zambelli-Weiner Exhibit No. 11</p> <p>6 was marked for identification.)</p> <p>7 BY MR. HEGARTY:</p> <p>8 Q It's not the same title, is it?</p> <p>9 A I see that. You're correct.</p> <p>10 Q That's a mistake in your CV, right?</p> <p>11 A That is. Thank you for bringing it to</p> <p>12 my attention.</p> <p>13 Q Is your -- with that mistake, is your CV</p> <p>14 still reliable?</p> <p>15 MS. PARFITT: Objection.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q Do you consider your CV still reliable?</p> <p>18 A I consider my CV representative of my</p> <p>19 work, yes.</p> <p>20 Q Do you still consider it a reliable CV?</p> <p>21 A I don't -- I don't understand the</p> <p>22 question.</p> <p>23 Q Well, is it -- is it a CV that we can</p> <p>24 rely upon to properly tell us about your work</p> <p>25 experience and the things that you've done in your</p>
<p style="text-align: right;">Page 59</p> <p>1 with" -- "neuroblastoma associated with</p> <p>2 carcinogens from a munitions factory: A toxic</p> <p>3 tort litigation case." Do you see that?</p> <p>4 A I'm sorry, where are you?</p> <p>5 Q The bottom of page 57.</p> <p>6 MR. TISI: There's a 57 on both of the</p> <p>7 exhibits, so I just want to make -- which one are</p> <p>8 you talking about?</p> <p>9 MR. HEGARTY: Exhibit No. 9.</p> <p>10 THE WITNESS: "A persistent worldwide</p> <p>11 environmental hazard," is that the one?</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q Let me see what you're looking at.</p> <p>14 You're looking at Exhibit 10. Exhibit</p> <p>15 No. 9.</p> <p>16 A Oh, I'm sorry. Okay.</p> <p>17 Q Do you see at the very bottom there's a</p> <p>18 paper entitled "Risk of neuroblastoma associated</p> <p>19 with carcinogens from munitions factory: A toxic</p> <p>20 tort litigation case"?</p> <p>21 A Yes, I do.</p> <p>22 Q There's no paper by that name at that --</p> <p>23 published in that journal with that citation, is</p> <p>24 there?</p> <p>25 A There should be.</p>	<p style="text-align: right;">Page 61</p> <p>1 career?</p> <p>2 A Yes.</p> <p>3 Q Now, your report defines what you</p> <p>4 reviewed and relied on in the sense that on</p> <p>5 page 46 of your report you list "Work cited."</p> <p>6 A I'm sorry, where are you?</p> <p>7 Q Let me start again.</p> <p>8 On page 46 of your report, you list</p> <p>9 "Work cited," correct?</p> <p>10 A Correct.</p> <p>11 Q On page 48, you list "Other documents</p> <p>12 considered," correct?</p> <p>13 A Correct.</p> <p>14 Q Are the materials under "Other documents</p> <p>15 considered" those that you reviewed that you</p> <p>16 didn't rely on for purposes of your report?</p> <p>17 A These would be documents that I received</p> <p>18 and reviewed.</p> <p>19 Q And what is the difference between</p> <p>20 the -- what you call "work cited" and what you</p> <p>21 call "other documents considered"?</p> <p>22 A What it should be is the "work cited"</p> <p>23 would be referenced within the body of the -- of</p> <p>24 the report.</p> <p>25 Q And "other documents considered," in</p>

Page 62	Page 64
<p>1 what way did you consider other documents for</p> <p>2 purposes of your report, the other documents</p> <p>3 listed?</p> <p>4 A I would just have reviewed them in some</p> <p>5 capacity.</p> <p>6 Q What did it take for -- strike that.</p> <p>7 For purposes of your opinions, did you</p> <p>8 rely on the documents listed under "Other</p> <p>9 documents considered"?</p> <p>10 A I would just say that I considered them.</p> <p>11 They're not cited within the body of my report.</p> <p>12 Q With regard to the documents that you</p> <p>13 included in the body of your report, did you rely</p> <p>14 on any particular document more than others or</p> <p>15 documents more than others?</p> <p>16 A I -- I'm not sure I understand the</p> <p>17 question.</p> <p>18 Q Well, were there any particular</p> <p>19 documents that you cited that you relied upon more</p> <p>20 than others or were the principal documents you</p> <p>21 relied upon, are you able to identify any of</p> <p>22 those?</p> <p>23 A Well, I think obviously the focus of my</p> <p>24 report is on the research products of</p> <p>25 Dr. Huncharek and Muscat. Hopefully I'm saying</p>	<p>1 A Correct.</p> <p>2 Q And would it -- is it separated out into</p> <p>3 a separate file where you can pull the drive and</p> <p>4 see that these were the documents provided by</p> <p>5 plaintiffs' counsel?</p> <p>6 A No.</p> <p>7 Q Is there any way to parse out from the</p> <p>8 list of documents the documents you received from</p> <p>9 plaintiffs' counsel?</p> <p>10 A Not as I sit here today.</p> <p>11 Q In the section of your report entitled</p> <p>12 "Methodology" on page 9 -- I'll let you get there.</p> <p>13 A Thank you. Mm-hmm.</p> <p>14 Q So I'll start over. In the section</p> <p>15 entitled "Methodology" on page 9, you state that</p> <p>16 you had access to publicly available documents.</p> <p>17 Do you see that, the second line under</p> <p>18 "Methodology" section?</p> <p>19 A Oh, sorry. Thank you. Yes.</p> <p>20 Q But you make no mention in this section</p> <p>21 or anywhere in your report of the details or</p> <p>22 methods of any literature searches you performed.</p> <p>23 Is that correct?</p> <p>24 A I didn't perform literature searches as</p> <p>25 part of this report, in a systematic way that you</p>
Page 63	Page 65
<p>1 their names correctly. So I guess in the way that</p> <p>2 you're asking that, I would agree that perhaps I</p> <p>3 relied on them more because they were the focus.</p> <p>4 Q Which of the studies that you list in</p> <p>5 your report were provided to you by plaintiffs'</p> <p>6 counsel?</p> <p>7 A That I cannot answer.</p> <p>8 Q Did -- were you -- did plaintiffs'</p> <p>9 counsel provide you with a notebook or electronic</p> <p>10 file of doc- -- of medical literature or</p> <p>11 documents?</p> <p>12 MR. TISI: Objection.</p> <p>13 THE WITNESS: They provided me with some</p> <p>14 documents. I don't recall what -- what came from</p> <p>15 them and what came from me.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q Did they provide those to you in a</p> <p>18 notebook form, electronic form or some other form?</p> <p>19 A Electron -- electronic. Sorry.</p> <p>20 Q Do you still have the electronic form in</p> <p>21 which the documents were provided to you?</p> <p>22 A That's what I provided on the drive.</p> <p>23 Q So the drive that you provided to us</p> <p>24 would have the documents that you received from</p> <p>25 plaintiffs' counsel.</p>	<p>1 do literature searches.</p> <p>2 Q Well, did you perform any type of</p> <p>3 literature search yourself in connection with</p> <p>4 preparing your report?</p> <p>5 A I'm sure I searched the literature, yes.</p> <p>6 Q Did you in any way set out in your</p> <p>7 report the methodology by which you used to search</p> <p>8 the literature?</p> <p>9 A No, because that wouldn't have been</p> <p>10 appropriate. It wasn't a literature review -- it</p> <p>11 wasn't a report based on a literature review.</p> <p>12 Q Well, was searching the literature part</p> <p>13 of your methodology for preparing your report?</p> <p>14 A No. I wouldn't say so.</p> <p>15 Q Then why did you do it?</p> <p>16 A I may have done it to supplant my -- my</p> <p>17 knowledge or I might have been curious about</p> <p>18 something that I found, and I would look it up.</p> <p>19 Q But no part of the methodology for</p> <p>20 preparing your report involved searching of the</p> <p>21 medical literature; is that what you're saying?</p> <p>22 A Correct. With -- I just want to</p> <p>23 clarify, with the caveat that that wasn't part of</p> <p>24 my -- my charge and what I was doing, so I</p> <p>25 wouldn't have put a protocol in place. The report</p>

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<p style="text-align: right;">Page 66</p> <p>1 doesn't contain a systematic or comprehensive 2 literature review of any topic. 3 Q The literature review was not necessary 4 for you to prepare your report; is that correct? 5 A You're -- you're -- I'm afraid I can't 6 answer that correctly. Well, I'm not 7 understanding your question. 8 Q Sure. 9 A Because you're using "literature review" 10 in an ambiguous way. 11 Q Well, was a literature search and the 12 review of the literature from that search 13 necessary for purposes of preparing your report? 14 A I would say probably some literature 15 review was necessary. I -- I probably in the 16 course of preparing my report needed or wanted to 17 pull a piece of literature to support the writing 18 of my report, but my report was not a literature 19 review. 20 Q Is it your testimony that you -- that a 21 proper methodology for doing a report would only 22 that -- strike that. 23 Is it your testimony that a literature 24 review is only a methodology for preparing a 25 report if you're doing a review kind of analysis?</p>	<p style="text-align: right;">Page 68</p> <p>1 review all the documents that discuss or reference 2 the 2003 or 2007 papers that you talk about in 3 your report? 4 MR. TISI: Objection. 5 THE WITNESS: Can you repeat that, 6 please? 7 BY MR. HEGARTY: 8 Q Sure. 9 Was it part of your methodology to 10 review all of the documents in the medical 11 literature that discuss or reference the 2003 and 12 2007 papers you talk about in your report? 13 A No, that was not the focus of my report. 14 Q With regard to the papers you did review 15 to prepare your report, we just looked at pages 46 16 and 48. Is that the totality of the papers that 17 you reviewed in connection with preparing your 18 report? 19 A You're referring to the -- to the "Work 20 Cited"? 21 Q And the "Other Documents Considered" 22 sections. 23 A I would say, again, these lists were 24 prepared to the best of my ability with the 25 references and sources that are cited in my report</p>
<p style="text-align: right;">Page 67</p> <p>1 A Well, sure. There's lots -- there's 2 lots of types of reviews. If I want to go into 3 PubMed and search for something, that doesn't 4 require a protocol. If I'm setting out to 5 undertake a project that will involve literature 6 review as part of that project, then that would be 7 part of that protocol. 8 Q Okay. Did you actually do the 9 literature searches on publicly available 10 websites? 11 A Yes. 12 Q What publicly available websites did you 13 search? 14 A Typically PubMed and Google Scholar. 15 Q And you don't in your report describe 16 the literature searches you did in terms of what 17 words or phrases you looked for, correct? 18 A No, because that wouldn't have been 19 appropriate. 20 Q And you didn't describe in your report 21 the literature search engines or publicly 22 available resources that you searched, correct? 23 A Correct, because, again, this wasn't a 24 literature review. 25 Q Well, was it part of your methodology to</p>	<p style="text-align: right;">Page 69</p> <p>1 and that I reviewed in preparation of my report. 2 Q Did you prepare these references as 3 well? Yourself, did you prepare the "Work Cited" 4 and the "Other Documents Considered" part of your 5 report? 6 A These -- the "Work Cited" part lives in 7 a -- a database management software, so that's 8 accessible by -- by everyone. But, yes, it does 9 get dropped in by me. 10 Q How about the "Other Documents 11 Considered," did you prepare that? 12 A I believe so, yes. 13 Q Did you review the totality of -- of all 14 of the papers that are referenced in both 15 sections? In other words, did you review the 16 entirety of every paper cited? 17 A No, definitely not. 18 Q Did you ever just read the abstracts? 19 A I couldn't say for sure. 20 Q But you can say for sure that you didn't 21 review every page of every document you cite in 22 this report. 23 A That's correct. 24 Q Had you read the papers by Dr. Huncharek 25 and Dr. Muscat referenced in your report before</p>

<p style="text-align: right;">Page 70</p> <p>1 being hired as an expert in this case?</p> <p>2 A Any -- can you clarify that question?</p> <p>3 Q Well, you talk about a 2003 and a 2007</p> <p>4 paper and a 2011 paper in your report, correct?</p> <p>5 A Correct.</p> <p>6 Q You mentioned those were the focus of</p> <p>7 your report, correct?</p> <p>8 A Correct.</p> <p>9 MR. TISI: Well, objection. Misstates.</p> <p>10 BY MR. HEGARTY:</p> <p>11 Q Had you read those papers before being</p> <p>12 contacted by Mr. Rotman about working as an expert</p> <p>13 on this litigation?</p> <p>14 A I can't recall. They're old papers.</p> <p>15 Q You say you can't -- you don't know one</p> <p>16 way or the other whether you had read them?</p> <p>17 A I -- I don't. I really don't.</p> <p>18 Q So you think it's more likely than not</p> <p>19 that you hadn't read them before being contacted</p> <p>20 by Mr. Rotman?</p> <p>21 MR. TISI: Objection. Calls for</p> <p>22 speculation.</p> <p>23 THE WITNESS: I really don't -- I don't</p> <p>24 recall.</p> <p>25 BY MR. HEGARTY:</p>	<p style="text-align: right;">Page 72</p> <p>1 A I -- I believe I had.</p> <p>2 Q Which ones had you read?</p> <p>3 A I don't recall.</p> <p>4 Q Are you able to recall any of the</p> <p>5 case-control studies you had read before being</p> <p>6 contacted by Mr. Rotman, the first names of the</p> <p>7 authors or the last names of the authors, the</p> <p>8 names, any of those?</p> <p>9 A No.</p> <p>10 Q Had you read all of the meta-analysis of</p> <p>11 the case-control studies concerning talc and</p> <p>12 ovarian cancer before being hired -- or before</p> <p>13 being contacted by Mr. Rotman?</p> <p>14 A Can you repeat, please?</p> <p>15 Q Sure.</p> <p>16 Had you read all of the meta-analysis of</p> <p>17 the case-control studies concerning talc and</p> <p>18 ovarian cancer before being contacted by</p> <p>19 Mr. Rotman about working on this litigation?</p> <p>20 A No, I don't believe I would have read</p> <p>21 all of them.</p> <p>22 Q Had you read any of them?</p> <p>23 A It's possible I had read some of them.</p> <p>24 Q Can you say under oath that you had read</p> <p>25 any of them?</p>
<p style="text-align: right;">Page 71</p> <p>1 Q Well, when you read them for the first</p> <p>2 time in connection with preparing your report, did</p> <p>3 you recall seeing them in the past?</p> <p>4 A Not specifically.</p> <p>5 Q Was there anything about them that rang</p> <p>6 a bell and -- or reminded you that you had seen</p> <p>7 these before?</p> <p>8 A Not necessarily, but I read a lot of</p> <p>9 literature.</p> <p>10 Q Before being contacted by Mr. Rotman,</p> <p>11 had you ever heard of Dr. Huncharek?</p> <p>12 A I don't know.</p> <p>13 Q Had you ever heard of Dr. Muscat?</p> <p>14 A His name sounded familiar, so I may</p> <p>15 have.</p> <p>16 Q Had -- you may have. You can't say one</p> <p>17 way or the other?</p> <p>18 A No.</p> <p>19 Q Had you read all the case-control</p> <p>20 studies, population-based and hospital-based</p> <p>21 studies regarding whether there's an association</p> <p>22 between talc use and ovarian cancer before being</p> <p>23 contacted by Mr. Rotman?</p> <p>24 A No, I'm sure I didn't.</p> <p>25 Q Had you read any of them?</p>	<p style="text-align: right;">Page 73</p> <p>1 A I can't say for certain.</p> <p>2 Q As to those you may have read, can you</p> <p>3 identify any of those today?</p> <p>4 A No.</p> <p>5 Q Had you read all of them through today?</p> <p>6 A No, probably not.</p> <p>7 Q Have you read all the case-control</p> <p>8 studies concerning talc and ovarian cancer through</p> <p>9 today?</p> <p>10 A I may have read -- I've at least --</p> <p>11 well, I can't say I've -- I've read all of them</p> <p>12 for sure, no.</p> <p>13 Q Had you read all of the prospective</p> <p>14 cohort studies on talc and ovarian cancer before</p> <p>15 being contacted by Mr. Rotman about working on</p> <p>16 this litigation?</p> <p>17 A I can't say for sure.</p> <p>18 Q Are you able to testify whether you had</p> <p>19 read any of them before being contacted by</p> <p>20 Mr. Rotman?</p> <p>21 A I really can't say. It's an old</p> <p>22 literature.</p> <p>23 Q So what does that mean when you say,</p> <p>24 "It's an old literature"?</p> <p>25 A It -- it goes back pretty far.</p>

<p style="text-align: right;">Page 74</p> <p>1 Q Well, one of the cohort studies goes</p> <p>2 back to 2014. Are you aware of that?</p> <p>3 A Sure. But I'm just saying as a</p> <p>4 literature, it's an old literature.</p> <p>5 Q So you consider literature from 2014 to</p> <p>6 be old literature?</p> <p>7 MR. TISI: Objection.</p> <p>8 THE WITNESS: I'm speaking of the body</p> <p>9 of literature on the topic, the epi studies.</p> <p>10 BY MR. HEGARTY:</p> <p>11 Q Had you read all the animal studies on</p> <p>12 talc and ovarian cancer before being contacted by</p> <p>13 Mr. Rotman?</p> <p>14 A No.</p> <p>15 Q Have you reviewed the animal studies</p> <p>16 through today?</p> <p>17 A No.</p> <p>18 Q Have you read any of the cell studies on</p> <p>19 talc and ovarian cancer by the time that you were</p> <p>20 contacted by Mr. Rotman?</p> <p>21 A I -- I may have.</p> <p>22 Q Which cell studies had you read?</p> <p>23 A Your question is very broad. So I did</p> <p>24 work in the area of -- of cancer and inflammation</p> <p>25 prior to becoming an epidemiologist, so -- and</p>	<p style="text-align: right;">Page 76</p> <p>1 Q Have you read every word of their</p> <p>2 deposition testimony?</p> <p>3 A No, I haven't.</p> <p>4 Q Have you personally reviewed any parts</p> <p>5 of their deposition testimony?</p> <p>6 A Yes.</p> <p>7 Q Did someone else review their deposition</p> <p>8 testimony at TTI as well and help you with</p> <p>9 understanding what they had testified to?</p> <p>10 A No, I don't believe so.</p> <p>11 Q But the testimony that you read from</p> <p>12 those witnesses is just those depositions that you</p> <p>13 list in your report, correct?</p> <p>14 A I -- I don't understand the question.</p> <p>15 Q Sure. You list certain depositions in</p> <p>16 your report from Dr. Muscat, from Ms. Loretz and</p> <p>17 from Dr. Nicholson, correct?</p> <p>18 A Correct.</p> <p>19 Q That would be the totality of their</p> <p>20 testimony that you have been provided for purposes</p> <p>21 of your work on this case, correct?</p> <p>22 A To the best of my knowledge.</p> <p>23 Q That testimony came from counsel for</p> <p>24 plaintiffs, correct?</p> <p>25 A That -- I don't -- what is "that</p>
<p style="text-align: right;">Page 75</p> <p>1 during my time as an epidemiologist.</p> <p>2 Q Well, can you cite for us here today any</p> <p>3 of the -- any of the cell studies you had reviewed</p> <p>4 looking at talc and ovarian cancer before being</p> <p>5 contacted by Mr. Rotman?</p> <p>6 A I can't cite to any specifically.</p> <p>7 Q Had you read all of the cell studies</p> <p>8 concerning talc and ovarian cancer that have been</p> <p>9 published through today?</p> <p>10 A No, I have not read all of them.</p> <p>11 MR. TISI: We've been going -- when you</p> <p>12 get a breaking point, we've been going a little</p> <p>13 over an hour.</p> <p>14 THE WITNESS: I was just going to ask</p> <p>15 for a break, please.</p> <p>16 MR. HEGARTY: Okay. Let me ask -- let</p> <p>17 me ask just a --</p> <p>18 MR. TISI: No problem.</p> <p>19 MR. HEGARTY: -- couple more questions,</p> <p>20 and then we'll take a break.</p> <p>21 BY MR. HEGARTY:</p> <p>22 Q You cited to Dr. Muscat's and Linda</p> <p>23 Loretz's and Susan Nicholson's depositions in your</p> <p>24 report. Are you aware of that?</p> <p>25 A Yes.</p>	<p style="text-align: right;">Page 77</p> <p>1 testimony"?</p> <p>2 Q Well, the deposition transcripts you</p> <p>3 reviewed were provided by plaintiffs' counsel,</p> <p>4 correct?</p> <p>5 A Correct.</p> <p>6 Q Did you ask for any other deposition</p> <p>7 testimony for purposes of your work on your</p> <p>8 report?</p> <p>9 A I can't recall if I had asked for any.</p> <p>10 MR. HEGARTY: All right. We can take a</p> <p>11 break. Go off the record.</p> <p>12 THE VIDEOGRAPHER: The time is 10:10</p> <p>13 a.m., and we're going off the record.</p> <p>14 (Recess.)</p> <p>15 THE VIDEOGRAPHER: The time is</p> <p>16 10:28 a.m. We're back on the record.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q Doctor, we're back on the record.</p> <p>19 Focusing on your report, which we've</p> <p>20 marked as Exhibit No. 8, is it correct that all of</p> <p>21 the opinions set out in your report concerning the</p> <p>22 Huncharek, Muscat works, the PCP response, were</p> <p>23 formed after being contacted by Mr. Rotman in this</p> <p>24 case, correct?</p> <p>25 A Yes, that's correct.</p>

<p style="text-align: right;">Page 78</p> <p>1 Q You had not done any comprehensive 2 analysis or developed any opinions about those 3 works before being contacted by Mr. Rotman, 4 correct? 5 A Correct. 6 Q Can you cite for us on any occasion in a 7 non-litigation situation when you have done the 8 exact same thing you have done here as to the 9 Huncharek and Huncharek and Muscat papers, that 10 is, where you listed as you do here in your report 11 what you contend are deficiencies in an 12 epidemiologic study or other study? 13 A Can you repeat? I lost the beginning of 14 that question. 15 Q Sure. 16 Well, in a non-litigation situation, 17 have you ever done the same thing that you've done 18 here as to the Huncharek and Muscat papers? 19 A Oh, absolutely, all the time. 20 Q As to epidemio- -- published 21 epidemiology work looking at case-control 22 studies? 23 MR. TISI: I -- 24 THE WITNESS: I don't understand the 25 question.</p>	<p style="text-align: right;">Page 80</p> <p>1 answered. 2 THE WITNESS: Not as I sit here, but I 3 can certainly get that to you. 4 BY MR. HEGARTY: 5 Q Can you cite for me any published paper, 6 like the Huncharek and Muscat diaphragm study, 7 where you have done the exact same thing in -- 8 outside of litigation that you have done in your 9 report? 10 A Again, this is an evaluation of the 11 internal validity of an epi study, and that's 12 something that I do every day in the course of my 13 work. 14 Q So every day in the course of your work, 15 you're looking at published epidemiologic studies 16 and doing the same thing that you have done in 17 your report? 18 A Absolutely. 19 Q And even though you do it every day, you 20 can't cite a single study sitting here today? 21 A No, I can't. I -- I have 20 to 30 22 active projects at a time. 23 Q And did you do this -- did you do last 24 week what you did in your report for a published 25 epidemiologic study?</p>
<p style="text-align: right;">Page 79</p> <p>1 BY MR. HEGARTY: 2 Q Well, the Muscat and Huncharek studies 3 or papers that you referred to -- well, strike. 4 Let me be specific. The Huncharek 2003 5 paper is a published meta-analysis, correct? 6 A Correct. 7 Q When outside of litigation have you ever 8 done what you do -- have done in your report as to 9 the Huncharek 2003 paper? 10 A All the time in the daily course of my 11 work. 12 Q Cite for me one published meta-analysis 13 where you have done the exact same thing that you 14 have done in your report. 15 A Cite one published meta-analysis -- I 16 can't think of a specific paper, but in the course 17 of my work, I do evidence synthesis for nearly 18 every project that I work on. 19 Q Well, I am asking -- so you -- sitting 20 here today, you can't cite a single published 21 paper in the medical literature of a meta-analysis 22 where you have done the exact same thing outside 23 of litigation as you have done for the 2003 24 Huncharek paper? 25 MR. TISI: Objection. Asked and</p>	<p style="text-align: right;">Page 81</p> <p>1 A I have ongoing projects where I'm doing 2 this exact same thing, yes. 3 Q So even though you did it last week, you 4 can't cite for me any published paper that you're 5 working on or have worked on? 6 A No. As I said, I mean I can't recall a 7 specific title, a specific author, but I can 8 certainly get you examples. 9 Q Cite for me any client or company that 10 you have -- have done this for. 11 A Well, I can't cite proprietary 12 companies, but Centers for Disease Control and 13 Prevention. 14 Q Cite for me one published article where 15 you have done the same thing as -- that you did 16 for the 2003 Huncharek paper for the CDC. 17 A I can give you bodies of literature. 18 Would you -- would you like that? I can't -- 19 can't name a specific title and author. 20 Q All right. Tell me what -- 21 A I just read so much literature and work 22 on so many projects, that's just unreasonable. 23 Q Tell me what body of literature. 24 A Blood pressure thresholds -- 25 effectiveness of blood -- blood pressure</p>

<p style="text-align: right;">Page 82</p> <p>1 thresholds. Excuse me.</p> <p>2 Q And those -- that body of literature</p> <p>3 concerns case-control studies, observational</p> <p>4 studies?</p> <p>5 A Yes.</p> <p>6 Q And what was your -- was your work</p> <p>7 product where you're critiquing the -- the way the</p> <p>8 study was done, the -- whether each of the study</p> <p>9 -- where the study reported data properly, that</p> <p>10 was what you have done?</p> <p>11 A Correct. It was an analysis of the</p> <p>12 internal validity of a body of epi studies.</p> <p>13 Q And how many times have you done that?</p> <p>14 A I couldn't possibly say.</p> <p>15 MR. TISI: For that -- for the blood</p> <p>16 pressure thing or overall?</p> <p>17 MR. HEGARTY: Overall.</p> <p>18 THE WITNESS: I don't know. Accumulate</p> <p>19 over 20 years of work, evaluation of epidemiologic</p> <p>20 studies, thousands of times.</p> <p>21 BY MR. HEGARTY:</p> <p>22 Q And you've done thousands of reports</p> <p>23 like you've -- we've marked as Exhibit No. 8?</p> <p>24 A Well, I certainly haven't testified in</p> <p>25 litigation thousands of times, so the answer would</p>	<p style="text-align: right;">Page 84</p> <p>1 that you have reviewed, again not considering</p> <p>2 litigation but in the medical literature,</p> <p>3 concerning talc and ovarian cancer before being</p> <p>4 contacted by Mr. Rotman?</p> <p>5 A No, again, I couldn't recall.</p> <p>6 Q Had you formed any opinions about talc</p> <p>7 and ovarian cancer before being contacted by</p> <p>8 Mr. Rotman?</p> <p>9 A I can't recall.</p> <p>10 Q Can you identify any materials in the</p> <p>11 published medical literature you had reviewed</p> <p>12 concerning talc and ovarian cancer before being</p> <p>13 contacted by Mr. Rotman?</p> <p>14 A No, I can't recall.</p> <p>15 Q Before being contacted by Mr. Rotman,</p> <p>16 you had never written anything about talc,</p> <p>17 correct?</p> <p>18 A I don't believe so.</p> <p>19 Q Before being contacted by Mr. Rotman,</p> <p>20 you had never offered in writing any opinions</p> <p>21 about talc, correct?</p> <p>22 A No, I'm going to say I -- I can't</p> <p>23 recall.</p> <p>24 Q Sitting here today, can you cite for us</p> <p>25 any written work that you have ever authored that</p>
<p style="text-align: right;">Page 83</p> <p>1 be no.</p> <p>2 Q Well, have you done in -- for any of the</p> <p>3 work with the CDC or other clients where you</p> <p>4 prepared a report like you prepared Exhibit No. 8?</p> <p>5 A I certainly have prepared work products</p> <p>6 that have relied upon the analysis of the internal</p> <p>7 validity of an epi study that I conducted.</p> <p>8 Q When did you first become aware of an</p> <p>9 alleged link between ovarian cancer and talc use?</p> <p>10 MR. TISI: Objection. Asked and</p> <p>11 answered.</p> <p>12 THE WITNESS: I can't recall.</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q Well, previously I had asked you about</p> <p>15 what you're aware of in the litigation. Now I'm</p> <p>16 broadening that.</p> <p>17 When -- what knowledge did you have of</p> <p>18 any alleged link between talc use and ovarian</p> <p>19 cancer from any source? Or strike that.</p> <p>20 When did you have knowledge of any -- of</p> <p>21 an alleged link between talc and ovarian cancer</p> <p>22 from any source before being contacted by</p> <p>23 Mr. Rotman?</p> <p>24 A I don't know.</p> <p>25 Q Do you know of any source of information</p>	<p style="text-align: right;">Page 85</p> <p>1 talks about talc?</p> <p>2 A I can't. I can't recall. It's</p> <p>3 possible.</p> <p>4 Q Well, can you cite for us any written</p> <p>5 work that you have ever done concerning any</p> <p>6 cosmetic product?</p> <p>7 A Not that's published to my knowledge,</p> <p>8 but certainly I've done work products on cosmetic</p> <p>9 products.</p> <p>10 Q What kind of cosmetic products?</p> <p>11 A Beauty, hygiene products.</p> <p>12 Q Give me an example.</p> <p>13 A Hair care products: Shampoo,</p> <p>14 conditioner.</p> <p>15 Q What kind of work?</p> <p>16 A Also facial cleansers.</p> <p>17 Q What kind of work?</p> <p>18 A Evidence synthesis, health hazard</p> <p>19 assessments and evaluations.</p> <p>20 Q It's correct you've never offered any</p> <p>21 opinions in writing about ovarian cancer, correct?</p> <p>22 A Not to my knowledge.</p> <p>23 Q You've never offered in writing any</p> <p>24 opinions about talc and ovarian cancer, correct?</p> <p>25 A I believe that's correct.</p>

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<p style="text-align: right;">Page 86</p> <p>1 Q You've never offered in writing any -- a</p> <p>2 discussion about the causes of ovarian cancer,</p> <p>3 correct?</p> <p>4 A Wait. Can you repeat the prior</p> <p>5 question, please?</p> <p>6 Q You've never offered in writing any</p> <p>7 opinions about talc and ovarian cancer before</p> <p>8 being contacted by Mr. Rotman, correct?</p> <p>9 MR. TISI: Okay.</p> <p>10 THE WITNESS: Thank you.</p> <p>11 MR. TISI: With that caveat.</p> <p>12 THE WITNESS: Yes.</p> <p>13 MR. TISI: Thank you.</p> <p>14 THE WITNESS: Correct.</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q And before being contacted by</p> <p>17 Mr. Rotman, you never offered in writing a</p> <p>18 discussion about the causes of ovarian cancer,</p> <p>19 correct?</p> <p>20 A Not that I can recall.</p> <p>21 Q And you've never published anywhere on</p> <p>22 the risk factors for ovarian cancer, correct?</p> <p>23 A I don't believe so.</p> <p>24 Q You've never spoken to an audience about</p> <p>25 the causes of ovarian cancer, correct?</p>	<p style="text-align: right;">Page 88</p> <p>1 courses?</p> <p>2 A I did them in the past when I was at</p> <p>3 Hopkins, and I've currently been nominated for</p> <p>4 adjunct status to -- to continue teaching there</p> <p>5 again.</p> <p>6 Q Was that a formal course that you taught</p> <p>7 on how to do meta-analysis?</p> <p>8 A No, it wasn't specifically on</p> <p>9 meta-analysis. It would have been embedded within</p> <p>10 a larger curriculum.</p> <p>11 Q Well, was this a course over the</p> <p>12 entirety of a semester?</p> <p>13 A I don't recall.</p> <p>14 Q Have you ever published on how to do a</p> <p>15 meta-analysis?</p> <p>16 A I don't believe so. I have published</p> <p>17 meta-analyses, though.</p> <p>18 Q How many times have you published a</p> <p>19 meta-analysis?</p> <p>20 A I'm not sure. I've done hundreds of</p> <p>21 meta-analyses, but not nearly that many</p> <p>22 publications.</p> <p>23 Q Well, look at your CV and tell me what</p> <p>24 publications you've done that are a meta-analysis.</p> <p>25 A (Peruses document.)</p>
<p style="text-align: right;">Page 87</p> <p>1 A I don't believe so. I'm really trying</p> <p>2 to think back.</p> <p>3 Q And you certainly never set out the</p> <p>4 opinions in your report in any peer-reviewed</p> <p>5 publication, correct?</p> <p>6 A Correct.</p> <p>7 Q Your report is not peer reviewed, right?</p> <p>8 A Correct.</p> <p>9 Q You purport to comment on a</p> <p>10 meta-analysis conducted by Dr. Huncharek and</p> <p>11 others. Have you ever taught on how to do a</p> <p>12 meta-analysis?</p> <p>13 A Yes, I have.</p> <p>14 Q Where have you taught on how to do a</p> <p>15 meta-analysis?</p> <p>16 A I've taught at Hopkins, and I have</p> <p>17 taught internally. I mentor a lot of</p> <p>18 epidemiologists, so I've taught there as well.</p> <p>19 Q Who have you taught at Johns Hopkins</p> <p>20 about how to do a meta-analysis?</p> <p>21 A I've -- doctoral students, graduate</p> <p>22 students, and I'm -- I'm also in the process of</p> <p>23 going to teach a class that will involve</p> <p>24 discussion and teaching of meta-analysis.</p> <p>25 Q And when did you do these teaching</p>	<p style="text-align: right;">Page 89</p> <p>1 So there's a 2018 paper in the Annals of</p> <p>2 Surgical Oncology that's a meta-analysis.</p> <p>3 Q That is a --</p> <p>4 A It's --</p> <p>5 Q That's not a meta-analysis on a case --</p> <p>6 on case-control studies, is it?</p> <p>7 A I don't recall what studies contributed</p> <p>8 to that.</p> <p>9 Q Well, it's a -- it's a "Meta-Analysis of</p> <p>10 Local Invasive Breast Cancer Recurrence After</p> <p>11 Electron Intraoperative Radiotherapy," correct?</p> <p>12 A Correct.</p> <p>13 Q That looked at rates of recurrence using</p> <p>14 a particular type of radiotherapy, correct?</p> <p>15 A That's correct.</p> <p>16 Q And that did not involve case-control</p> <p>17 studies, correct?</p> <p>18 A As I said, I don't recall the nature of</p> <p>19 the studies that were in that analysis.</p> <p>20 Q Well, the studies concern looking at</p> <p>21 recurrence rates, correct?</p> <p>22 A Yes, that's correct.</p> <p>23 Q You did that for a company, right?</p> <p>24 A Correct.</p> <p>25 Q The company was decision -- was IntraOp</p>

<p style="text-align: right;">Page 90</p> <p>1 Medical, right?</p> <p>2 A That's correct.</p> <p>3 Q And they actually had a radiotherapy</p> <p>4 that was included as part of this analysis, right?</p> <p>5 A Yeah, they have a product that related</p> <p>6 to the analysis, yes, but it -- I don't believe</p> <p>7 that was like a limited scope of the analysis.</p> <p>8 Q Your analysis came out with that their</p> <p>9 product was the best at limiting recurrence rate,</p> <p>10 correct?</p> <p>11 A I don't know that that's correct. We</p> <p>12 could look at the paper if -- if you'd like.</p> <p>13 Q But the study was paid by for IntraOp</p> <p>14 Medical?</p> <p>15 A That's correct.</p> <p>16 Q And you included that in your</p> <p>17 acknowledgment, right?</p> <p>18 A Yes, I believe so.</p> <p>19 Q And was that -- did the fact that they</p> <p>20 paid for that analysis influence the results?</p> <p>21 A No.</p> <p>22 Q Did you try to influence the results of</p> <p>23 regulators by preparing that paper?</p> <p>24 A The paper was not submitted to</p> <p>25 regulators.</p>	<p style="text-align: right;">Page 92</p> <p>1 literature.</p> <p>2 Q What was?</p> <p>3 A The Accutane presentation.</p> <p>4 Q That was actually an abstract, right?</p> <p>5 A Correct.</p> <p>6 Q You are -- was that abstract peer</p> <p>7 reviewed?</p> <p>8 A Yes, it was.</p> <p>9 Q It was peer reviewed as part of what?</p> <p>10 A I'm looking. (Peruses document.) Where</p> <p>11 is it?</p> <p>12 American Public Health Association.</p> <p>13 Q That was part of -- at their annual</p> <p>14 meeting, right?</p> <p>15 A Correct.</p> <p>16 Q It was not published beyond the book</p> <p>17 that was prepared for that annual meeting, was it?</p> <p>18 A I don't recall.</p> <p>19 Q And you were -- at the time you gave</p> <p>20 this public -- this presentation, you had been a</p> <p>21 litigation expert for plaintiffs in the Accutane</p> <p>22 litigation, correct?</p> <p>23 A That's correct.</p> <p>24 Q Did you disclose that in your abstract?</p> <p>25 A I believe so, yes.</p>
<p style="text-align: right;">Page 91</p> <p>1 Q Well, did you try to influence the</p> <p>2 medical community with regard to the use of</p> <p>3 electron intraoperative radiotherapy by preparing</p> <p>4 this article?</p> <p>5 MR. TISI: Objection.</p> <p>6 THE WITNESS: I think we were submitting</p> <p>7 evidence into the evidence base. To what extent</p> <p>8 that influences the medical community, I would</p> <p>9 certainly hope that that's the point of publishing</p> <p>10 peer-reviewed literature.</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q Do you consider it okay to have a paper</p> <p>13 funded by industry?</p> <p>14 A Absolutely.</p> <p>15 Q Can you cite for me any other</p> <p>16 meta-analysis you've done in the published medical</p> <p>17 literature?</p> <p>18 A I believe there is a presentation -- let</p> <p>19 me look. (Peruses document.)</p> <p>20 There was a presentation on that same</p> <p>21 topic, and let me look. I believe there was an</p> <p>22 Accutane presentation as well.</p> <p>23 Q I'm talking about meta-analysis that's</p> <p>24 in the published medical literature.</p> <p>25 A Well, that was in the published medical</p>	<p style="text-align: right;">Page 93</p> <p>1 Q And if you didn't, that would have been</p> <p>2 improper, right?</p> <p>3 A Correct.</p> <p>4 Q Is it your opinion that meta-analysis</p> <p>5 can amplify biases in -- in the individual</p> <p>6 studies?</p> <p>7 MR. TISI: Objection. Beyond the scope.</p> <p>8 THE WITNESS: I would say again it's</p> <p>9 always hard with just a one-liner out of context,</p> <p>10 but I would say, yes, I agree with that.</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q You agree that meta-analyses don't</p> <p>13 correct bias and confounding in the underlying</p> <p>14 studies, correct?</p> <p>15 MR. TISI: Objection. Beyond the scope.</p> <p>16 THE WITNESS: Can you repeat, please?</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q Sure. You agree that meta-analyses</p> <p>19 don't correct bias and confounding in the</p> <p>20 underlying studies.</p> <p>21 MR. TISI: Same objection.</p> <p>22 THE WITNESS: I don't -- I don't really</p> <p>23 understand that statement.</p> <p>24 BY MR. HEGARTY:</p> <p>25 Q Well, meta-analysis combines --</p>

<p style="text-align: right;">Page 94</p> <p>1 A Out of context, it's hard.</p> <p>2 Q Meta-analysis combines the work of other</p> <p>3 published studies into one study, correct?</p> <p>4 A Correct.</p> <p>5 Q Doing that meta-analysis, if there are</p> <p>6 biases and confounding in the underlying studies</p> <p>7 don't correct those biases and confounding,</p> <p>8 correct?</p> <p>9 MR. TISI: Objection. Beyond the scope.</p> <p>10 You can answer.</p> <p>11 THE WITNESS: I would say generally,</p> <p>12 yes, I agree with that.</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q If the underlying studies are poor, the</p> <p>15 meta-analysis will not improve them, correct?</p> <p>16 MR. TISI: Objection. Beyond the scope.</p> <p>17 THE WITNESS: That's -- that's a very</p> <p>18 ambiguous question.</p> <p>19 Could you rephrase?</p> <p>20 BY MR. HEGARTY:</p> <p>21 Q Sure. If the underlying studies are</p> <p>22 poor due to bias and confounding, the</p> <p>23 meta-analysis will not improve those underlying</p> <p>24 studies, correct?</p> <p>25 MR. TISI: Objection. Beyond the scope.</p>	<p style="text-align: right;">Page 96</p> <p>1 meta-analysis. I simply tried to replicate</p> <p>2 numbers, which is a very different thing.</p> <p>3 Q Have you ever conducted a case study?</p> <p>4 A A case study?</p> <p>5 Q Sure. You comment about the Huncharek</p> <p>6 and Muscat 2011 case study. Have you ever done</p> <p>7 such a case study?</p> <p>8 A Can you clarify how you're using "case</p> <p>9 study"?</p> <p>10 Q Well, let me ask it a different way.</p> <p>11 Have you ever published in the medical literature</p> <p>12 a review article?</p> <p>13 A I believe so, yes.</p> <p>14 Q Well, cite for me from your CV any</p> <p>15 published review article you have written.</p> <p>16 A Perhaps I should back up. How are you</p> <p>17 defining "a review article"?</p> <p>18 Q Well, a review article is an article, as</p> <p>19 I understand it, that looks at a body of medical</p> <p>20 literature and talks about it and comments on it,</p> <p>21 like Drs. Huncharek and Muscat did in the 2011</p> <p>22 paper.</p> <p>23 A Well, there's lots of types of review</p> <p>24 papers, so that's a very broad designation.</p> <p>25 Q Have you ever done a type of review</p>
<p style="text-align: right;">Page 95</p> <p>1 THE WITNESS: The meta-analysis is -- is</p> <p>2 simply a synthesis of those studies, so whatever</p> <p>3 strength and limitations existed within the</p> <p>4 studies will still be there.</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q A proper meta-analysis must analyze</p> <p>7 sources of heterogeneity across the studies,</p> <p>8 correct?</p> <p>9 A That's correct.</p> <p>10 Q And a proper meta-analysis must examine</p> <p>11 the methodology of each underlying individual</p> <p>12 study. You said that before, correct?</p> <p>13 A Correct.</p> <p>14 Q Did you do -- did you analyze the</p> <p>15 individual -- the methodology of each individual</p> <p>16 study in your reanalysis of the 2003 and 2007</p> <p>17 papers?</p> <p>18 A Well, I wasn't doing an independent</p> <p>19 meta-analysis. I was simply attempting to</p> <p>20 replicate one. So I didn't go through that</p> <p>21 process.</p> <p>22 Q So you did not do a -- a meta-analysis</p> <p>23 of the -- of the data in the 2003 or 2007 papers</p> <p>24 in your report, correct?</p> <p>25 A I did not do an independent</p>	<p style="text-align: right;">Page 97</p> <p>1 paper that the same -- along the same lines that</p> <p>2 Dr. Huncharek and Dr. Muscat did in 2011 in the</p> <p>3 published literature?</p> <p>4 A I'm not sure. I'd have to go back and</p> <p>5 look.</p> <p>6 Q Can you cite for me anything from your</p> <p>7 CV where you have done a paper along the lines of</p> <p>8 the 2011 Huncharek and Muscat paper?</p> <p>9 A Define "along the lines."</p> <p>10 Q Well, that is similar to what they did.</p> <p>11 A I can't answer that. It's too -- that's</p> <p>12 too vague. I don't know what you're really asking</p> <p>13 me.</p> <p>14 Q Well, cite for me any published medical</p> <p>15 literature you've done where you've reviewed a</p> <p>16 body of literature.</p> <p>17 A Sure. A lot.</p> <p>18 Q Cite for me one example.</p> <p>19 A Okay.</p> <p>20 (Interruption by cell phone.)</p> <p>21 A Oh, shoot, I'm sorry. Excuse me. It</p> <p>22 won't turn off. Sorry about that.</p> <p>23 So just starting at the top --</p> <p>24 MR. TISI: Are you looking at the</p> <p>25 current CV? I just want to know what you're</p>

<p style="text-align: right;">Page 98</p> <p>1 looking at. Are you looking at the current CV --</p> <p>2 THE WITNESS: Oh, I'm sorry.</p> <p>3 MR. TISI: There's three that are</p> <p>4 marked, and I just want to make sure I'm looking</p> <p>5 at the right one.</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q And you can just give me one example of</p> <p>8 where you have published an article reviewing a</p> <p>9 body of medical literature.</p> <p>10 MR. TISI: But she's looking at her CV,</p> <p>11 and I just want to know which one she's looking at</p> <p>12 because you marked three.</p> <p>13 MR. HEGARTY: I don't care whether she's</p> <p>14 looking at the CV or not.</p> <p>15 THE WITNESS: I don't -- could you</p> <p>16 repeat your prior question, please?</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q Sure.</p> <p>19 I wanted you to cite for me one</p> <p>20 published medical article where you have reviewed</p> <p>21 the body of literature on a topic.</p> <p>22 A Sure. The CD14 paper.</p> <p>23 Q Did you recently do an article on</p> <p>24 Zofran?</p> <p>25 A Yes, I did.</p>	<p style="text-align: right;">Page 100</p> <p>1 us.</p> <p>2 Q And how much did it cost to do that</p> <p>3 article?</p> <p>4 A I don't know. I'd have to quantify</p> <p>5 that.</p> <p>6 Q Do you know what an h-index is?</p> <p>7 A H-index?</p> <p>8 Q An h-index.</p> <p>9 A I'm not sure.</p> <p>10 Q Do you have an h-index?</p> <p>11 A I don't -- I'm not sure as I sit here</p> <p>12 what an h-index is.</p> <p>13 Q Are you a peer reviewer for any</p> <p>14 journals?</p> <p>15 A I am.</p> <p>16 Q On page 55 of your CV, you list three</p> <p>17 journals you say you've peer reviewed for; is that</p> <p>18 correct?</p> <p>19 A Correct.</p> <p>20 Q And how many times have you peer</p> <p>21 reviewed for those journals?</p> <p>22 A Maybe half a dozen.</p> <p>23 Q For each journal?</p> <p>24 A No, in total.</p> <p>25 Q You've never been a peer reviewer for</p>
<p style="text-align: right;">Page 99</p> <p>1 Q Was that paid for by lawyers for the</p> <p>2 plaintiffs in the Zofran litigation?</p> <p>3 A No, it wasn't.</p> <p>4 Q So they didn't provide any funding for</p> <p>5 that paper.</p> <p>6 A They did not.</p> <p>7 Q Who provided the funding for the paper?</p> <p>8 A I did.</p> <p>9 Q You personally paid for it?</p> <p>10 A Yes, I did.</p> <p>11 Q Are you a retained expert for plaintiffs</p> <p>12 in the Zofran litigation?</p> <p>13 A No, I'm not.</p> <p>14 Q You've received no money from</p> <p>15 plaintiffs' lawyers as part of work on the Zofran</p> <p>16 litigation.</p> <p>17 A That's correct.</p> <p>18 Q Why did you pay for yourself to do that</p> <p>19 article?</p> <p>20 A I have a -- a longstanding interest in</p> <p>21 birth defects, and we have a program within our</p> <p>22 company to do work in this area and grow work in</p> <p>23 this area. We have a five-year, \$4 million</p> <p>24 contract with the National Center for Birth</p> <p>25 Defects, and so this is a big area of focus for</p>	<p style="text-align: right;">Page 101</p> <p>1 the European Journal of Cancer Prevention,</p> <p>2 correct?</p> <p>3 A I -- I don't believe so.</p> <p>4 Q You've never published in that journal,</p> <p>5 right?</p> <p>6 A I don't believe so.</p> <p>7 Q What were its peer review procedures</p> <p>8 back in 2011 or 2007, do you know?</p> <p>9 A I don't know. I don't know. I'm not</p> <p>10 even sure what you're asking.</p> <p>11 Q Well, what were the peer review</p> <p>12 procedures for any articles submitted to the</p> <p>13 European Journal of Cancer Prevention back in</p> <p>14 2007?</p> <p>15 A Typically they have instructions to</p> <p>16 authors online. I don't know as I sit here what</p> <p>17 they are.</p> <p>18 Q Have you ever been a peer reviewer for</p> <p>19 Anti-Cancer Research?</p> <p>20 A No, I don't believe so.</p> <p>21 Q Have you ever published in that journal?</p> <p>22 A No, I don't believe so.</p> <p>23 Q Do you know the peer review procedures</p> <p>24 for that journal?</p> <p>25 A Not as I sit here. Again, I'm sure</p>

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<p style="text-align: right;">Page 102</p> <p>1 they're readily available.</p> <p>2 Q Have you ever been a reviewer for a NIH</p> <p>3 grant proposal?</p> <p>4 A Yes, I have.</p> <p>5 Q How many times?</p> <p>6 A One -- one major time where I sat on a</p> <p>7 panel. I'm not sure if I've reviewed grants</p> <p>8 outside of that.</p> <p>9 Q Was it your testimony that if we go</p> <p>10 online and look at the NIH website for those who</p> <p>11 have submitted grants that your name will appear?</p> <p>12 A It should. Although I don't know --</p> <p>13 Q What grant --</p> <p>14 A I don't know how long it goes back.</p> <p>15 Q What grant was that?</p> <p>16 A It was for the National Eye Institute.</p> <p>17 Q What year was that?</p> <p>18 A I don't recall.</p> <p>19 Q Have you ever been on an editorial board</p> <p>20 for a journal?</p> <p>21 A No, I haven't.</p> <p>22 Q Have you ever been designated as an</p> <p>23 expert witness for a defendant in a lawsuit?</p> <p>24 A I have not been designated as an expert</p> <p>25 witness, no.</p>	<p style="text-align: right;">Page 104</p> <p>1 A I don't recall what his background is.</p> <p>2 Q You're not part of the medical</p> <p>3 community, right?</p> <p>4 MR. TISI: Objection.</p> <p>5 THE WITNESS: I wouldn't -- I wouldn't</p> <p>6 characterize it that way. I would say I'm not an</p> <p>7 MD. I'm not a physician.</p> <p>8 BY MR. HEGARTY:</p> <p>9 Q Well, you're -- you don't consider</p> <p>10 yourself to be a part of the medical community, do</p> <p>11 you?</p> <p>12 A I consider -- that's a vague -- it</p> <p>13 depends how you define "medical community."</p> <p>14 Q Well, are you a healthcare provider?</p> <p>15 A No, I'm not.</p> <p>16 Q Dr. Huncharek is a radiologist,</p> <p>17 oncologist. You're not an oncologist, right?</p> <p>18 A Correct.</p> <p>19 Q You're not a radiologist, right?</p> <p>20 A Correct.</p> <p>21 Q You have no training in oncology, right?</p> <p>22 A I have no training in clinical oncology.</p> <p>23 Q You have no training in radiology,</p> <p>24 correct?</p> <p>25 A I have no training in radiology. I'm</p>
<p style="text-align: right;">Page 103</p> <p>1 Q Has your testimony ever been excluded by</p> <p>2 a court?</p> <p>3 A Yes, I believe it has been excluded</p> <p>4 one -- one time.</p> <p>5 Q It was excluded in the Accutane</p> <p>6 litigation, correct?</p> <p>7 A That's correct.</p> <p>8 Q It was also excluded in part in the</p> <p>9 Mirena litigation too, right?</p> <p>10 A Well, I believe the accurate</p> <p>11 characterization of that is my -- my testimony was</p> <p>12 limited to only the testimony I intended to give.</p> <p>13 So...</p> <p>14 Q But your testimony was excluded in its</p> <p>15 entirety in the Accutane litigation, right?</p> <p>16 A That's correct. My understanding is</p> <p>17 that's under appeal.</p> <p>18 Q Did you read the court's opinion</p> <p>19 excluding your testimony?</p> <p>20 A I may have at one point in time.</p> <p>21 Q Doctor, you're not a medical doctor,</p> <p>22 correct?</p> <p>23 A Correct.</p> <p>24 Q Dr. Huncharek is a medical doctor. Are</p> <p>25 you aware of that?</p>	<p style="text-align: right;">Page 105</p> <p>1 just clarifying. That doesn't mean I don't have</p> <p>2 training in research related to these -- to these</p> <p>3 areas.</p> <p>4 Q You've never diagnosed or treated a</p> <p>5 disease in a patient, including cancer, correct?</p> <p>6 A That's correct, because I'm not a</p> <p>7 physician.</p> <p>8 Q You have no expertise in treating</p> <p>9 patients with ovarian cancer, correct?</p> <p>10 A That's correct.</p> <p>11 Q You have no expertise in diagnosing</p> <p>12 ovarian cancer, right?</p> <p>13 A I have no experience as a physician</p> <p>14 diagnosing ovarian cancer.</p> <p>15 Q Have you ever diagnosed ovarian cancer</p> <p>16 in a patient?</p> <p>17 A I haven't diagnosed ovarian cancer, but</p> <p>18 it's sort of a slippery slope. I'm just leaving</p> <p>19 it open for -- as it relates to research.</p> <p>20 Q You're not a cell biologist, right?</p> <p>21 A I don't characterize myself as a -- as a</p> <p>22 bench scientist, but I have done work in that</p> <p>23 area.</p> <p>24 Q You've done cell studies?</p> <p>25 A Yes, I have.</p>

27 (Pages 102 to 105)

<p style="text-align: right;">Page 106</p> <p>1 Q Using what kind of cells?</p> <p>2 A I don't recall. It was at the National</p> <p>3 Cancer Institute. It's been a while now.</p> <p>4 Q You're not a pathologist, are you?</p> <p>5 A I'm not.</p> <p>6 Q Not a geneticist?</p> <p>7 A I'm not a clinical geneticist, but I do</p> <p>8 have a Ph.D. in human genetics.</p> <p>9 Q You're not a mineralogist, correct?</p> <p>10 A That's correct.</p> <p>11 Q You're not an expert on talc, right?</p> <p>12 MR. TISI: Objection.</p> <p>13 THE WITNESS: I'm not a -- the mineral</p> <p>14 talc?</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q Yes.</p> <p>17 A Can you clarify that question?</p> <p>18 Q Sure.</p> <p>19 A No, I'm not an expert on the mineral</p> <p>20 talc.</p> <p>21 Q You're not an expert on asbestos,</p> <p>22 correct?</p> <p>23 MR. TISI: Objection.</p> <p>24 THE WITNESS: I -- I would agree I'm not</p> <p>25 an expert on asbestos as a -- as a mineral,</p>	<p style="text-align: right;">Page 108</p> <p>1 expert qualified to study that relationship if I</p> <p>2 chose to do so.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q You're not an expert on in vitro</p> <p>5 testing, are you?</p> <p>6 A No.</p> <p>7 Q You're not an expert on in vivo testing?</p> <p>8 A Again, I would back up and clarify the</p> <p>9 prior answer and say I wouldn't characterize</p> <p>10 myself as an expert, but I have worked in those</p> <p>11 areas --</p> <p>12 Q You've never done --</p> <p>13 A -- in the past.</p> <p>14 Q I'm sorry. You've never done animal</p> <p>15 studies, have you?</p> <p>16 A Yes, I have.</p> <p>17 Q Over what animal species?</p> <p>18 A I've worked with mice and rats.</p> <p>19 Q Doing what kind of experiments?</p> <p>20 A Doing studies of inflammation.</p> <p>21 Q Involving what exposure?</p> <p>22 MR. TISI: I'm sorry, she was not</p> <p>23 finished.</p> <p>24 BY MR. HEGARTY:</p> <p>25 Q Were you finished?</p>
<p style="text-align: right;">Page 107</p> <p>1 correct.</p> <p>2 BY MR. HEGARTY:</p> <p>3 Q Well, you're not an expert on talc and</p> <p>4 its use in -- well, strike that.</p> <p>5 You're not an expert on talc and any</p> <p>6 potential medical effects of talc, correct?</p> <p>7 MR. TISI: Objection.</p> <p>8 THE WITNESS: I would consider myself an</p> <p>9 expert in methodology as it might relate to that</p> <p>10 kind of a question.</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q But how about specifically as it relates</p> <p>13 to talc and any potential medical effects of talc,</p> <p>14 you're not an expert on those, correct?</p> <p>15 MR. TISI: Objection.</p> <p>16 THE WITNESS: Could you rephrase the</p> <p>17 question?</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q Sure.</p> <p>20 You're not an expert on talc and ovarian</p> <p>21 cancer, correct?</p> <p>22 MR. TISI: Objection.</p> <p>23 THE WITNESS: I wouldn't characterize</p> <p>24 myself as an expert on talc and ovarian cancer,</p> <p>25 but again, I certainly would consider myself an</p>	<p style="text-align: right;">Page 109</p> <p>1 A No.</p> <p>2 Q Go ahead.</p> <p>3 A Studies of mechanisms of inflammation.</p> <p>4 Q Involving exposure to any substance?</p> <p>5 A No.</p> <p>6 Q You're not an industrial hygienist, are</p> <p>7 you?</p> <p>8 A No.</p> <p>9 Q You're not an FDA expert, correct?</p> <p>10 MR. TISI: Objection.</p> <p>11 THE WITNESS: I am not -- correct, I'm</p> <p>12 not a regulatory expert.</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q You're not an expert on the properties</p> <p>15 of talc, correct?</p> <p>16 A Correct.</p> <p>17 Q With regard to ovarian cancer, what are</p> <p>18 the subtypes of the disease?</p> <p>19 A Let's see. I know there's -- I'll do my</p> <p>20 best to recall. I know there's epithelial and</p> <p>21 nonepithelial. Within epithelial, I know there is</p> <p>22 mucinous and -- I'm blanking on -- on the other</p> <p>23 subtypes at the moment.</p> <p>24 Q Do you know what the most common subtype</p> <p>25 of ovarian cancer is?</p>

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<p style="text-align: right;">Page 110</p> <p>1 A Epithelial I believe makes up the 2 majority. 3 Q How about -- that's not a subtype, 4 though. 5 A Oh, you said type. 6 Q It's a type of ovarian cancer. 7 A Right. I don't recall at the moment. 8 Q Dr. Muscat is a full professor at Penn 9 State. Dr. Huncharek was an adjunct assistant 10 professor at the University of South Carolina 11 School of Medicine. 12 Do you currently hold any faculty 13 positions? 14 A I don't currently hold, but as I said, 15 I'm -- my -- I've been nominated for adjunct 16 status at Hopkins, and that's currently in 17 process. 18 Q Have you ever held a faculty position at 19 a university? 20 A No, I haven't. Other than during my 21 time at Hopkins. 22 Q That was not a faculty position. 23 A I wouldn't call that faculty, no. 24 That's correct. 25 Q If you look at the qualifications</p>	<p style="text-align: right;">Page 112</p> <p>1 MR. HEGARTY: Okay. Well, I mean I can 2 take a break now or we can wait until I move 3 through this section. 4 MR. TISI: It's up to her. 5 MR. HEGARTY: Which should be five or 6 ten minutes. It's up to you. 7 THE WITNESS: I'll give it a whirl. Go 8 ahead. 9 BY MR. HEGARTY: 10 Q Okay. If you look at the 11 "Qualifications" section, in the second paragraph 12 you say that you're a methodological expert. Do 13 you see that? 14 A Yes. 15 Q That's a self-proclaimed title, correct? 16 MR. TISI: Objection. 17 THE WITNESS: Well, I wouldn't agree 18 with that characterization of it. This is what 19 clients hire me and my company to do, so I think 20 the expertise is recognized. 21 BY MR. HEGARTY: 22 Q Well, has any group, entity or person 23 recognized you in any published setting as a 24 methodological expert? 25 A It's possible. I don't know what you</p>
<p style="text-align: right;">Page 111</p> <p>1 section of your report that starts on page -- 2 A Actually, sorry, can I just clarify? 3 Because I was on staff at Hopkins, so I don't know 4 what -- I don't know what definition of "faculty" 5 you're using, but I'm just going to clarify that. 6 Q You've never been a professor at any 7 university, correct? 8 A Correct. 9 Q Or an assistant professor? 10 A That's correct. 11 Q Or an adjunct professor? 12 A Correct. 13 Q If you look at the "Qualifications" 14 section of yours on page 5 of your report. 15 A I'm really sorry, but after this 16 question I need another break. Sorry. 17 Q How much longer can you go? 18 MR. TISI: I don't think she should have 19 to -- if she needs to take a break -- 20 MR. HEGARTY: No, no, I'm saying my -- 21 the next several questions might take five 22 minutes. I don't have just question, but other -- 23 otherwise, it's a break point. 24 THE WITNESS: If it's that, I'll power 25 through.</p>	<p style="text-align: right;">Page 113</p> <p>1 mean by "a published setting." 2 Q Well, have you ever been characterized 3 in any published work as a methodological expert? 4 A I don't know about that. 5 Q Have you ever been given this title by 6 anyone but yourself? 7 A Sure. Yeah, absolutely. 8 Q Name somebody who has called you a 9 methodological expert. 10 A The faculty at Johns Hopkins who want me 11 to come teach. 12 Q Give me a name. 13 A They're in the Center for Biomedical 14 Engineering. I can tell you that. I'm just 15 blanking on the name at the minute because it's a 16 difficult one. I can get it for you, especially 17 on a break. 18 Q So sitting here today, you can't name 19 anyone who has ever called you a methodological 20 expert? 21 A Not at the moment. Again, I don't know 22 what you mean by called me. I think expertise is 23 recognized in a multitude of ways. 24 Q Well, I -- I'm sorry. 25 A And building a business on -- on</p>

<p style="text-align: right;">Page 114</p> <p>1 epidemiology and methodology I think is a 2 recognition of the expertise. 3 Q Well, I'm being specific to the phase 4 you use in your report, "methodological expert." 5 Who has ever called you a methodological expert in 6 epidemiology and public health? 7 A I'm sure my clients have. 8 Q Can you name for me any person that's 9 ever called you that? 10 A Some of the lawyers sitting here today. 11 Q Okay. Anybody else? Can you name any 12 specific person from a client, not a lawyer. 13 A Well, I can't name client names. 14 Q Why can't you name client names? 15 A Confidentiality. 16 Q So the name of a person you work with 17 you consider to be confidential? 18 A Sure. Well, I mean I'm -- I'm bound by 19 confidentiality agreements, and what I do for them 20 is -- is often confidential. 21 Q So you're -- you think those 22 confidentiality agreements extend to simply 23 identifying the person with whom you have 24 communicated with? 25 A Sure.</p>	<p style="text-align: right;">Page 116</p> <p>1 that you were at Johns Hopkins? 2 A 2003 or '4. 3 Q Okay. And have you ever taught any 4 courses on methodological expertise of 5 epidemiology and public health since working at 6 Hopkins? 7 A I have not taught any academic courses, 8 no. 9 Q And have you written any articles 10 setting out in detail this methodological 11 expertise that you have? 12 A Could you be more specific? 13 Q Sure. You say you're a methodological 14 expert. In any written publication, have you ever 15 explained in what way you're a methodological 16 expert? 17 A I don't know. I don't know how or why 18 that would happen, but -- I don't think so. 19 Q What special training have you had to 20 become a methodological expert beyond any other 21 person who is a trained epidemiologist? 22 A All of my training and years of 23 experience. Ph.D. and post-doc at Johns Hopkins, 24 20 years of experience working in the field, and 25 building a multimillion dollar consulting firm</p>
<p style="text-align: right;">Page 115</p> <p>1 Q When in any written -- strike that. 2 This -- this claim of a methodological 3 expert, is that on your website anywhere? 4 A I don't know. 5 Q When in any written work have you called 6 yourself a methodological expert? Can you cite 7 for me any written work where you've used that 8 phrase? 9 A I'm not sure. 10 Q Have you ever taught courses on this 11 methodological expertise? 12 A I think we -- I think we talked about 13 that a little bit already. 14 Q How long ago was that? 15 A That's been a while. During my time at 16 Hopkins. Because, of course, I'm in the 17 commercial sector, so my day-to-day livelihood 18 does not involve teaching, but it does involve 19 mentoring. 20 Q Are you -- you're -- 21 A And as I -- 22 Q Sorry, I thought you were finished. 23 A No, I just wanted to -- to reiterate 24 that -- that I am going to be teaching. 25 Q Well, you're -- when is the last time</p>	<p style="text-align: right;">Page 117</p> <p>1 from nothing based on my skills, expertise and 2 reputation as well as my -- my larger team. 3 Q And again, going back to what special 4 training do you have besides -- beyond what an 5 epidemiologist would have at -- at Johns Hopkins? 6 MR. TISI: Objection. Calls for 7 speculation. 8 BY MR. HEGARTY: 9 Q Do you consider yourself a 10 methodological expert who has had training beyond 11 an epidemiologist at Johns Hopkins? 12 MR. TISI: Objection. Asked and -- 13 THE WITNESS: I don't understand the 14 question. 15 MR. TISI: Asked and answered. 16 BY MR. HEGARTY: 17 Q Well, what -- what training allows you 18 to say you're a methodological expert? 19 A What -- what allows anyone to say 20 they -- they're an expert? That you are 21 accomplished, that you are recognized and -- and 22 valued for those services, which I clearly am. I 23 have 20 years of experience working in the field 24 of epidemiology, beyond my Ph.D. and post-doc from 25 Johns Hopkins and the program that accepts three</p>

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<p style="text-align: right;">Page 118</p> <p>1 people a year. So, yes, I consider myself an 2 expert, and I think that's established. 3 Q But can you cite for us anybody out -- 4 besides in this room who considers yourself to be 5 a methodological expert? 6 MR. TISI: Objection. Asked and 7 answered -- 8 THE WITNESS: Yes. 9 MR. TISI: -- now about four times. 10 BY MR. HEGARTY: 11 Q Can you give us a name? 12 A The CDC that awarded my -- my company a 13 five-year contract for the National Center for 14 Chronic Disease. 15 Q At the top of page 6 of your report, you 16 claim that much of your work is focused on 17 diseases of inflammation. What published articles 18 of yours in your CV focuses on diseases of 19 inflammation? 20 A I have several publications on asthma, 21 several publications on cancer, diabetes, 22 cardiovascular disease. 23 Q And all of those publications concern 24 inflammation? 25 A Sure, at some level mechanisms of</p>	<p style="text-align: right;">Page 120</p> <p>1 Q You're not relying on any publication of 2 yours or a study you were involved in for purposes 3 of your opinions, correct? 4 A That's correct. 5 Q You had not seen any of the company 6 documents of J&J and Imerys before being hired by 7 the lawyers in this case, correct? 8 A I believe that's correct. 9 Q As to the company documents, you don't 10 personally know any of the -- of the individuals 11 who are referenced in those documents, do you? 12 A No, I don't. 13 Q You have not been involved in any group 14 that has examined the safety of talc, correct? 15 A Correct. 16 Q You've never worked for J&J, right? 17 A That's correct. 18 Q Never worked for Imerys? 19 A Correct. 20 Q You've never talked with anyone at J&J 21 or Imerys regarding talc, correct? 22 A Correct. 23 Q You've never talked with any other 24 company who makes talc about a talc product, 25 correct?</p>
<p style="text-align: right;">Page 119</p> <p>1 inflammation, yes. 2 Q And those publications would be set out 3 in your CV, correct? 4 A Correct. 5 MR. HEGARTY: Okay. We can take that 6 break if you want to. 7 THE WITNESS: Thanks. 8 THE VIDEOGRAPHER: The time is 11:06 9 a.m., and we're going off the record. 10 (Recess.) 11 THE VIDEOGRAPHER: The time is 11:21 12 a.m., and we're back on the record. 13 BY MR. HEGARTY: 14 Q Doctor, the opinions in your report are 15 based on your review of materials, your training 16 and your experience, correct? 17 A Correct. 18 Q You were not personally involved in any 19 of the studies that you cite in your report, 20 correct? 21 A That's correct. 22 Q You were not an author on any of the 23 studies you've cited or read and referenced in 24 your report, correct? 25 A That's correct.</p>	<p style="text-align: right;">Page 121</p> <p>1 A That's correct. I -- yes, I believe so. 2 Q You've had no involvement in the 3 development of any talc product, correct? 4 A Although -- well, can you repeat the 5 prior question? 6 Q Sure. You've never talked with any 7 company with which you have worked regarding a 8 talc product of theirs, correct? 9 A That's correct. 10 Q You've had no involvement in the 11 development of any talc product, correct? 12 A Correct. Well, I -- I -- not to my 13 knowledge. 14 Q You've never worked for FDA, right? 15 A That's correct. 16 Q You've never worked for any health 17 agency or authority, correct? 18 A I have worked for them as a contractor 19 but not as an employee. 20 Q You've never been part of a health 21 agency's health or safety assessment of any 22 product, correct? 23 MR. TISI: Objection. 24 THE WITNESS: I wouldn't say that's 25 entirely correct.</p>

<p style="text-align: right;">Page 122</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q What part is not correct?</p> <p>3 A I have worked with a health agency that</p> <p>4 evaluates the safety of chemicals and chemical</p> <p>5 ingredients.</p> <p>6 Q Well, have you been involved in that</p> <p>7 agency's health assessment? In other words, are</p> <p>8 you -- were you part of their team doing a health</p> <p>9 assessment or a safety assessment of a product?</p> <p>10 A No, I wasn't.</p> <p>11 MR. TISI: Objection.</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q You've never been involved in responding</p> <p>14 to a citizen petition, correct?</p> <p>15 A That's correct.</p> <p>16 Q You've never been part of FDA's review</p> <p>17 of a citizen petition, correct?</p> <p>18 A Correct.</p> <p>19 Q Have you ever submitted a response to a</p> <p>20 citizen petition?</p> <p>21 A I don't believe so.</p> <p>22 Q Have you ever worked with anyone in</p> <p>23 preparing a response to a citizen petition?</p> <p>24 A I don't believe so.</p> <p>25 Q Have you ever read -- had you ever read</p>	<p style="text-align: right;">Page 124</p> <p>1 Q Do you know what -- do you know what</p> <p>2 role each person at FDA played in terms of</p> <p>3 responding to the citizen petition?</p> <p>4 A No, I don't know what they did or</p> <p>5 exactly what their process was.</p> <p>6 Q Can you describe the expertise of any of</p> <p>7 the individuals at FDA who reviewed or were</p> <p>8 involved in reviewing the citizen petition?</p> <p>9 A Not as I sit here right now, no.</p> <p>10 Q Have you ever spoken to anyone at FDA</p> <p>11 about their review of the citizen petition?</p> <p>12 A No.</p> <p>13 Q Have you ever tried to speak to anybody</p> <p>14 at FDA about their review?</p> <p>15 A Could you be more specific?</p> <p>16 Q Sure. Have you ever tried to speak with</p> <p>17 anyone at FDA about their review of the 1994 and</p> <p>18 2008 citizen petitions regarding talc and ovarian</p> <p>19 cancer?</p> <p>20 A No.</p> <p>21 Q How much time did FDA spend in its</p> <p>22 review of the citizen petitions?</p> <p>23 A I don't know.</p> <p>24 Q Over what period of time did FDA do its</p> <p>25 review of the citizen petitions?</p>
<p style="text-align: right;">Page 123</p> <p>1 the rules and regulations regarding citizen</p> <p>2 petitions before being contacted by Mr. Rotman in</p> <p>3 this case?</p> <p>4 A That I don't know. I don't recall.</p> <p>5 Q As to the FDA's review of the 1994 and</p> <p>6 2008 citizen petitions on talc and ovarian cancer,</p> <p>7 can you name those at FDA who were involved in the</p> <p>8 analysis of those citizen petitions?</p> <p>9 A I believe -- let's see. I know I have</p> <p>10 it here, but if this is a memory test -- I -- Kapp</p> <p>11 maybe. I think he's the chair or deputy chair of</p> <p>12 the --</p> <p>13 MR. TISI: You're allowed to look at --</p> <p>14 THE WITNESS: Okay.</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q Let me ask a different question.</p> <p>17 A Yeah.</p> <p>18 Q Is the information you have as far as</p> <p>19 who was involved from the FDA's denial letter?</p> <p>20 A Correct.</p> <p>21 Q Do you have any information beyond</p> <p>22 what's in the FDA's denial letter in terms of</p> <p>23 names as far as who was involved in FDA in looking</p> <p>24 at the citizen petition?</p> <p>25 A No, I don't.</p>	<p style="text-align: right;">Page 125</p> <p>1 A All I know from the docket is that there</p> <p>2 were years that transpired, but I don't know how</p> <p>3 much time they spent on the review.</p> <p>4 Q Did FDA consult with any outside experts</p> <p>5 as part of this process of reviewing the citizen</p> <p>6 petitions in -- from 2008 and 1994?</p> <p>7 A I don't know.</p> <p>8 Q You had no involvement in FDA's review</p> <p>9 of the 2000 -- of the 1994 and 2008 citizen</p> <p>10 petitions, correct?</p> <p>11 A Correct.</p> <p>12 Q You have no personal knowledge of FDA's</p> <p>13 work in responding to the citizen petitions,</p> <p>14 correct?</p> <p>15 A Only what's publicly available.</p> <p>16 Q You've had no involvement in anything</p> <p>17 that FDA has done as to talc, correct?</p> <p>18 MR. TISI: Objection.</p> <p>19 THE WITNESS: I've had no involvement</p> <p>20 with FDA regarding talc.</p> <p>21 BY MR. HEGARTY:</p> <p>22 Q Neither FDA nor any regulatory,</p> <p>23 scientific or other body has ever sought out your</p> <p>24 opinion on the scientific literature as to talc</p> <p>25 and ovarian cancer, correct?</p>

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<p style="text-align: right;">Page 126</p> <p>1 MR. TISI: Objection.</p> <p>2 THE WITNESS: Can you repeat that,</p> <p>3 please?</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q Sure. Neither FDA nor any other</p> <p>6 regulatory, scientific or other body has ever</p> <p>7 sought out your opinions on the scientific</p> <p>8 literature as to talc and ovarian cancer, correct?</p> <p>9 MR. TISI: Objection.</p> <p>10 THE WITNESS: I believe that's correct,</p> <p>11 yes.</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q You've never submitted anything to FDA</p> <p>14 or any other agency or group regarding talc,</p> <p>15 correct?</p> <p>16 A I believe that's correct.</p> <p>17 Q Or ovarian cancer, correct?</p> <p>18 A Can you repeat the question?</p> <p>19 Q Sure. You've never submitted anything</p> <p>20 to FDA or any other agency or group regarding</p> <p>21 ovarian cancer, correct?</p> <p>22 A I wouldn't say that's correct, no.</p> <p>23 Q What -- what part is incorrect?</p> <p>24 A Well, I've certainly been involved --</p> <p>25 you just said the word "submitted." I've</p>	<p style="text-align: right;">Page 128</p> <p>1 A I would call it critical review,</p> <p>2 critical epidemiological review.</p> <p>3 Q What is your definition of "general</p> <p>4 acceptance" of the medic -- of the scientific</p> <p>5 community?</p> <p>6 A That the methods are taught, conducted,</p> <p>7 published in textbooks. I mean I think anyone</p> <p>8 could come up with a range of -- of definitions</p> <p>9 for -- for "generally accepted," but certainly as</p> <p>10 a Ph.D. epidemiologist with 20 years of</p> <p>11 experience, I know what's generally accepted in</p> <p>12 the field of epidemiology.</p> <p>13 Q What did you do to confirm that the</p> <p>14 methods you employed are generally accepted?</p> <p>15 A I don't need to confirm them.</p> <p>16 They're -- they're just standard, fundamental</p> <p>17 epidemiologic methods that you can find in the</p> <p>18 Rothman textbook.</p> <p>19 Q Did you go and confirm that what you did</p> <p>20 was what is set out in, for example, the Rothman</p> <p>21 textbook?</p> <p>22 A I don't -- I don't need to do that. No.</p> <p>23 Q Did you survey scientists as far as what</p> <p>24 your method -- as far as the methodology you</p> <p>25 proposed -- you did to see if it was generally</p>
<p style="text-align: right;">Page 127</p> <p>1 certainly submitted things to agencies related to</p> <p>2 ovarian cancer.</p> <p>3 Q Okay. What have you submitted to</p> <p>4 agencies regarding ovarian cancer?</p> <p>5 A Proposals.</p> <p>6 Q Proposals as to what?</p> <p>7 A For studies.</p> <p>8 Q Studies on what?</p> <p>9 A Ovarian cancer.</p> <p>10 Q Ovarian cancer and what?</p> <p>11 A Surveys, survivorship issues.</p> <p>12 Q Have you published in those areas?</p> <p>13 A No.</p> <p>14 Q If you look at the "Methodology" section</p> <p>15 of your report on pages 9 and 10.</p> <p>16 A (Peruses document.)</p> <p>17 Q And in that last paragraph on page 9,</p> <p>18 you state that your analysis and -- and in</p> <p>19 formulating opinions, you employed methods that</p> <p>20 are generally accepted by the scientific</p> <p>21 community.</p> <p>22 Do you see that?</p> <p>23 A Yes, I do.</p> <p>24 Q Is there a name for the method that you</p> <p>25 employ, a formal name?</p>	<p style="text-align: right;">Page 129</p> <p>1 accepted by those scientists?</p> <p>2 A No. And I would certainly hope I -- I</p> <p>3 didn't have to do that or I would be in a lot of</p> <p>4 trouble.</p> <p>5 Q Where are the methods you employed</p> <p>6 published in the medical literature? You</p> <p>7 mentioned Rothman. Is -- is that one source?</p> <p>8 A Sure. I mean this is essentially an</p> <p>9 analysis of the internal validity of epidemiologic</p> <p>10 studies. So you can look up "internal validity"</p> <p>11 in any epi textbook.</p> <p>12 Q Have you ever published your methodology</p> <p>13 in any medical journal?</p> <p>14 A Can you be more specific?</p> <p>15 Q Well, you say that you employed</p> <p>16 methodologies that are generally accepted by the</p> <p>17 scientific community. Have you ever laid out in</p> <p>18 any medic- -- published medical article the</p> <p>19 methodology that is to be employed when you do</p> <p>20 what you do in this report, the steps?</p> <p>21 A Well, an assessment of the internal</p> <p>22 validity of a study is a component of any review</p> <p>23 of a study. So it's not a methodology per se as</p> <p>24 much as a process. It's, again, textbook</p> <p>25 epidemiology.</p>

<p style="text-align: right;">Page 130</p> <p>1 Q Have you ever published a chapter in a</p> <p>2 textbook laying out the methods for analyzing</p> <p>3 medical literature?</p> <p>4 A No, I haven't.</p> <p>5 Q Have you ever published in any medical</p> <p>6 article the methods for analyzing a medical</p> <p>7 journal, step-by-step methods?</p> <p>8 MR. TISI: Medical --</p> <p>9 MR. HEGARTY: I'm sorry.</p> <p>10 MR. TISI: Analyzing a medical journal?</p> <p>11 MR. HEGARTY: Yeah, let me repeat that.</p> <p>12 Should have just let my bad question go.</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q Have you ever published in a medical</p> <p>15 article the methods for analyzing the reliability,</p> <p>16 the validity, the accuracy of a medical article?</p> <p>17 A I don't know to what extent that might</p> <p>18 be in anything I published.</p> <p>19 Q Can you cite for me anything like that</p> <p>20 today?</p> <p>21 A No, not at the moment.</p> <p>22 Q Have you ever tested the accuracy of the</p> <p>23 results that you get from employing the methods</p> <p>24 that you used for purposes of your report?</p> <p>25 MR. TISI: Objection.</p>	<p style="text-align: right;">Page 132</p> <p>1 Q Do you intend to testify that either</p> <p>2 intended their work to improperly influence</p> <p>3 anyone?</p> <p>4 A I'm not testifying to intent. I'm --</p> <p>5 I'm testifying to fact.</p> <p>6 Q Do you intend to testify that the</p> <p>7 statements and conclusions that they made were</p> <p>8 intended to not reflect their honest review of the</p> <p>9 data but instead made to benefit J&J or Imerys?</p> <p>10 A No. As I said, I'm not testifying to</p> <p>11 their intent.</p> <p>12 Q Do you intend to testify that they were</p> <p>13 intentionally misleading in their work?</p> <p>14 A Again, no.</p> <p>15 Q Do you intend to testify that any errors</p> <p>16 or discrepancies cited in their report were done</p> <p>17 intentionally?</p> <p>18 A No.</p> <p>19 Q Have you ever filed or gave notice of</p> <p>20 any ethical complaint about an author of a</p> <p>21 publication?</p> <p>22 A I don't believe so.</p> <p>23 Q Have you filed or gave notice of any</p> <p>24 ethical complaints about Dr. Huncharek or</p> <p>25 Dr. Muscat?</p>
<p style="text-align: right;">Page 131</p> <p>1 THE WITNESS: Well, I think the validity</p> <p>2 of -- of -- I'm sorry, repeat the question.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q Sure. Have you ever tested the accuracy</p> <p>5 of the methodological approach that you -- you</p> <p>6 used for purposes of preparing your report?</p> <p>7 MR. TISI: Objection. Assumes --</p> <p>8 THE WITNESS: Can you define "accuracy"?</p> <p>9 That's not really a term I would apply to this.</p> <p>10 BY MR. HEGARTY:</p> <p>11 Q Have you ever developed a rate of error</p> <p>12 in applying the methodology that you imply -- you</p> <p>13 used for purposes of your report?</p> <p>14 A That isn't something that -- that we</p> <p>15 would do in epidemiology.</p> <p>16 Q If you look at Section 5.1 of your</p> <p>17 report on page 10, you refer to ethics guidelines</p> <p>18 by the American College of Epidemiologists. Do</p> <p>19 you see that?</p> <p>20 A I do.</p> <p>21 Q Do you intend to testify in this case</p> <p>22 that either Dr. Huncharek or Dr. Muscat were</p> <p>23 unethical in connection with any of their work?</p> <p>24 A No, I don't think that's what I'm</p> <p>25 testifying to.</p>	<p style="text-align: right;">Page 133</p> <p>1 A No.</p> <p>2 Q Have you ever been on a review board or</p> <p>3 panel involved in looking at claims of ethical</p> <p>4 violations in published literature?</p> <p>5 A No, I haven't.</p> <p>6 Q Do you intend to testify that either J&J</p> <p>7 or Imerys had any involvement in the works you</p> <p>8 discuss with the intent to influence anyone?</p> <p>9 A Again, I'm -- that's a compound</p> <p>10 question, but I'm just going to repeat, I'm not</p> <p>11 testifying to intent.</p> <p>12 Q Do you intend to testify that either J&J</p> <p>13 or Imerys were aware of the issues with the</p> <p>14 studies you cite in your report?</p> <p>15 MR. TISI: Objection.</p> <p>16 THE WITNESS: I'm sorry, can you repeat?</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q Sure. Do you intend to testify that</p> <p>19 either J&J or Imerys were -- were aware of the</p> <p>20 issues that you cite in your report with regard to</p> <p>21 any of the works you analyzed?</p> <p>22 A I don't know if they were aware of the</p> <p>23 issues.</p> <p>24 Q Do you intend to testify that the</p> <p>25 statements and conclusions made in -- I'm sorry.</p>

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<p style="text-align: right;">Page 134</p> <p>1 A Just give me one second. Sorry. Sorry,</p> <p>2 excuse me.</p> <p>3 Go ahead.</p> <p>4 Q Do you intend to testify that the</p> <p>5 statements and conclusions made in PCPC's 2009</p> <p>6 response to the citizen petition were intended to</p> <p>7 not reflect their honest review of the data but</p> <p>8 instead made to benefit J&J or Imerys?</p> <p>9 MR. TISI: Objection.</p> <p>10 THE WITNESS: I can't --</p> <p>11 MR. TISI: Compound question.</p> <p>12 THE WITNESS: I can't -- can you repeat?</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q Sure. Do you intend to testify that the</p> <p>15 statements and conclusions made in PCPC's response</p> <p>16 to the citizen petition, the 2009 response, were</p> <p>17 intended to not reflect their honest review of the</p> <p>18 data but instead made to benefit J&J or Imerys in</p> <p>19 the process?</p> <p>20 MR. TISI: Objection. Compound</p> <p>21 question.</p> <p>22 THE WITNESS: I'm not testifying to</p> <p>23 intent.</p> <p>24 BY MR. HEGARTY:</p> <p>25 Q Do you intend to testify that either J&J</p>	<p style="text-align: right;">Page 136</p> <p>1 Muscat on these papers, what you cite in your</p> <p>2 report, with an improper motive or intent to</p> <p>3 influence or mislead anyone, including FDA?</p> <p>4 MR. TISI: Objection. Compound.</p> <p>5 THE WITNESS: No.</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q In the middle of page 10 of your report,</p> <p>8 you say the reliability -- that reliability is the</p> <p>9 concept that results must be repeatable. Is that</p> <p>10 statement correct?</p> <p>11 A That's correct, in general, in</p> <p>12 scientific research, yes.</p> <p>13 Q So the word "reliability" is the concept</p> <p>14 that results must be repeatable. Is that the</p> <p>15 right phrase? It's not repeatable -- or</p> <p>16 replica -- or it's not replicability?</p> <p>17 A You could probably interchange --</p> <p>18 interchange that, but reliability is the concept</p> <p>19 that given the same protocol and the same set of</p> <p>20 circumstances, you would get the same results.</p> <p>21 Q In this section under "Transparency and</p> <p>22 Reproducibility," you also state that: "The</p> <p>23 reliability of scientific findings cannot be</p> <p>24 evaluated if research is not reported in a</p> <p>25 transparent and reproducible manner."</p>
<p style="text-align: right;">Page 135</p> <p>1 Imerys or PCPC were aware of the issues you cite</p> <p>2 in your report as to the Huncharek and Muscat</p> <p>3 analysis submitted in 2009?</p> <p>4 MR. TISI: Objection.</p> <p>5 THE WITNESS: That's a long question.</p> <p>6 I'm sorry, can you repeat?</p> <p>7 BY MR. HEGARTY:</p> <p>8 Q Sure. Do you intend to testify that</p> <p>9 either J&J, Imerys or PCPC were aware of the</p> <p>10 issues you cite in your report about the Muscat</p> <p>11 and Huncharek analysis that they submitted to FDA</p> <p>12 in 2009?</p> <p>13 A No, I don't know what they were aware</p> <p>14 of, so no.</p> <p>15 Q Do you intend to testify that PCPC, J&J</p> <p>16 or Imerys were misleading in their interactions</p> <p>17 with FDA?</p> <p>18 A No.</p> <p>19 Q Do you intend to testify that either</p> <p>20 PCPC, J&J or Imerys acted with an improper motive</p> <p>21 in communicating with FDA about talc and ovarian</p> <p>22 cancer?</p> <p>23 A Again, no, not testifying to intent.</p> <p>24 Q Do you intend to testify that either of</p> <p>25 these companies interacted with Drs. Huncharek and</p>	<p style="text-align: right;">Page 137</p> <p>1 Correct?</p> <p>2 A Correct.</p> <p>3 Q So according to you, the reliability of</p> <p>4 any work that is not reported in a completely</p> <p>5 transparent and reproducible manner cannot be</p> <p>6 evaluated, correct?</p> <p>7 MR. TISI: Objection.</p> <p>8 THE WITNESS: I think that's a poorly</p> <p>9 written sentence, which is what you're probably</p> <p>10 driving at. I think the point is you can't do,</p> <p>11 you know, a full evaluation of the rigor of a</p> <p>12 study if there aren't transparent methods and</p> <p>13 reporting of results, which is why it took so much</p> <p>14 effort to undertake the analysis that I did.</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q Well, is it your opinion that the 2003</p> <p>17 study by Dr. Huncharek was not reported in a</p> <p>18 completely transparent and reproducible manner?</p> <p>19 A Yes, it is.</p> <p>20 Q How about the 2007 paper?</p> <p>21 A Yes.</p> <p>22 Q How about the 2009 response to the</p> <p>23 citizen petition?</p> <p>24 A Can you --</p> <p>25 Q Sure. Was the --</p>

35 (Pages 134 to 137)

<p style="text-align: right;">Page 138</p> <p>1 A I lost the chain of the question there.</p> <p>2 Q Was the Huncharek and Muscat response to</p> <p>3 the citizens petition done in a completely</p> <p>4 transparent and reproducible manner?</p> <p>5 A I wouldn't talk about reproducibility in</p> <p>6 terms of a review paper, a weight of evidence type</p> <p>7 analysis. I'm talking about studies, statistical</p> <p>8 analyses, which would be the 2003 and 2007 papers.</p> <p>9 Q So we focused on the 2003 and 2007</p> <p>10 paper. By the definition you report here, you</p> <p>11 cannot even evaluate whether the papers were</p> <p>12 reliable, correct?</p> <p>13 A Well, that's your -- that's your</p> <p>14 interpretation of what I wrote, but I just</p> <p>15 explained what I meant.</p> <p>16 Q Well, according to your statement, you</p> <p>17 can't say one way or another whether these works</p> <p>18 are valid because, according to you, they're not</p> <p>19 trans- -- they're not done in a transparent or</p> <p>20 reproducible manner. I'm just using your words.</p> <p>21 A Right. And you're -- you're assigning</p> <p>22 your meaning to it, and I'm telling you my</p> <p>23 meaning.</p> <p>24 Q Again, what is your meaning besides what</p> <p>25 you write in your report?</p>	<p style="text-align: right;">Page 140</p> <p>1 correct?</p> <p>2 MR. TISI: Objection.</p> <p>3 THE WITNESS: No, I don't agree with how</p> <p>4 you said that.</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q Okay. Well, I guess we will let the</p> <p>7 record reflect your definition.</p> <p>8 Is it your opinion that unless</p> <p>9 everything an author does is spelled out in a</p> <p>10 study such that the exact same materials can be</p> <p>11 reviewed and the exact same analysis be done, the</p> <p>12 study is invalid and unreliable?</p> <p>13 A In general, I would not agree with that</p> <p>14 statement. I think that it's very contextually</p> <p>15 dependent. Certain types of studies, certain</p> <p>16 types of analyses require certain types of</p> <p>17 specification of the methods and reporting. So it</p> <p>18 really is quite a spectrum. It's very</p> <p>19 contextually dependent. Meta-analysis in</p> <p>20 particular has a lot of standards and best</p> <p>21 practices around it in terms of methods in</p> <p>22 reporting.</p> <p>23 Q And where are those standards and best</p> <p>24 practices laid out in the published literature?</p> <p>25 A You can look at the Cochrane</p>
<p style="text-align: right;">Page 139</p> <p>1 A My meaning is I can't fully evaluate the</p> <p>2 rigor of the results, and in a particular study,</p> <p>3 if there's not full transparent reporting of the</p> <p>4 methods and the results. So I can attempt -- I</p> <p>5 can do an analysis, I can attempt to replicate,</p> <p>6 but ultimately it remains unknown if you're unable</p> <p>7 to replicate what was done. So that leaves</p> <p>8 something unknown that should not be unknown.</p> <p>9 Q Okay. So you can't fully evaluate the</p> <p>10 rigor of the 2003 and 2007 papers, correct?</p> <p>11 MR. TISI: Objection.</p> <p>12 THE WITNESS: I did -- I did -- I did a</p> <p>13 full evaluation of those papers.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q Well, you just said you can't fully</p> <p>16 evaluate the rigor of a -- of the results of a</p> <p>17 study unless they're reported in a transparent and</p> <p>18 reproducible manner, correct?</p> <p>19 A Correct. So there's still some -- there</p> <p>20 are still some unknowns that -- that should not be</p> <p>21 unknown. That's -- that's the point being made.</p> <p>22 Q So you can't evaluate all -- all the</p> <p>23 rigors or knowns about the 2003 or 2007 papers</p> <p>24 because, according to you, they weren't done in a</p> <p>25 completely transparent and reproducible manner,</p>	<p style="text-align: right;">Page 141</p> <p>1 Collaboration. You can look at the PRISMA</p> <p>2 guidelines. You can look at PICO's.</p> <p>3 Q Is your opinion that errors in</p> <p>4 abstracting data render a report invalid or</p> <p>5 unreliable?</p> <p>6 A Again, it's the context of the errors.</p> <p>7 So errors in and of themselves and in the</p> <p>8 abstract, you can't really take them out of</p> <p>9 context. So it depends on the nature and the</p> <p>10 magnitude of the errors.</p> <p>11 Q Is that also true for misquoting of</p> <p>12 authorities?</p> <p>13 A I think I --</p> <p>14 MR. TISI: Objection.</p> <p>15 THE WITNESS: I think I did actually</p> <p>16 testify before to that exact thing. I think I</p> <p>17 said I would have to look at the totality of -- of</p> <p>18 the piece of work and the context.</p> <p>19 BY MR. HEGARTY:</p> <p>20 Q Is not following an author's methods</p> <p>21 that they lay out at the beginning of a</p> <p>22 publication and not following them as they said</p> <p>23 they would, does that -- does that make a study</p> <p>24 invalid or unreliable?</p> <p>25 MR. TISI: Objection.</p>

<p style="text-align: right;">Page 142</p> <p>1 THE WITNESS: I don't understand your</p> <p>2 question.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q Well, if an author lays out what they're</p> <p>5 going to do in a paper, and then doesn't do that</p> <p>6 in a paper, that's something different, does that</p> <p>7 make the paper invalid or unreliable?</p> <p>8 MR. TISI: Objection.</p> <p>9 THE WITNESS: Yes, I would say that it</p> <p>10 does. It certainly -- it certainly is a threat to</p> <p>11 validity.</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q Does cherry-picking the science make a</p> <p>14 report invalid and unreliable?</p> <p>15 A I don't know what you mean by -- by</p> <p>16 cherry-picking the science.</p> <p>17 Q Well, you know what "cherry-picking"</p> <p>18 means.</p> <p>19 A Well, I think different people have</p> <p>20 different meanings of it.</p> <p>21 Q What's your definition of</p> <p>22 "cherry-picking"?</p> <p>23 A I don't -- I don't usually use that</p> <p>24 word. If you want to give me your definition,</p> <p>25 I'll respond to it.</p>	<p style="text-align: right;">Page 144</p> <p>1 that situation?</p> <p>2 A It depends on the -- the nature of the</p> <p>3 review. Some reviews -- there's a gradient of</p> <p>4 rigor in reviews. Some reviews are not meant to</p> <p>5 be systematic or comprehensive. They're meant to</p> <p>6 be representative. And in that case, yes, you may</p> <p>7 select what you think is the best literature.</p> <p>8 Q How about in a systematic and</p> <p>9 comprehensive review, is it appropriate to</p> <p>10 cherry-pick in that situation?</p> <p>11 MR. TISI: Objection.</p> <p>12 THE WITNESS: I would say by definition</p> <p>13 not in a systematic review. A comprehensive</p> <p>14 review, you know, again, depends upon the nature</p> <p>15 of the review. I would say across the board it</p> <p>16 really depends on what the stated goal is and what</p> <p>17 the claim of cherry-picking is. I just really</p> <p>18 can't evaluate something in -- in abstract.</p> <p>19 BY MR. HEGARTY:</p> <p>20 Q Well, if an author is trying to do a</p> <p>21 systematic and comprehensive review, is it your</p> <p>22 opinion that it would be improper to cherry-pick</p> <p>23 in that situation?</p> <p>24 MR. TISI: Objection.</p> <p>25 THE WITNESS: Again, it depends on the</p>
<p style="text-align: right;">Page 143</p> <p>1 Q You've never heard that phrase before?</p> <p>2 A I have heard the phrase.</p> <p>3 Q And what is your understanding when you</p> <p>4 hear that phrase?</p> <p>5 A Selective examination of certain pieces</p> <p>6 of evidence, I suppose is a reasonable definition.</p> <p>7 Q Does doing that in a report or article</p> <p>8 make a report -- that report or article invalid</p> <p>9 and -- and unreliable?</p> <p>10 MR. TISI: Objection.</p> <p>11 THE WITNESS: Well, it depends on what</p> <p>12 the goals and objectives -- stated goals and</p> <p>13 objectives of the study analysis or report are.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q Well, in what -- when can you ever have</p> <p>16 a goal or objective that would allow you to</p> <p>17 cherry-pick the science?</p> <p>18 A When you have reasons to focus on</p> <p>19 particular studies, like studies that are</p> <p>20 submitted by sponsors to regulatory agencies.</p> <p>21 Q How about in a review article --</p> <p>22 A And I call that cherry-picking, by the</p> <p>23 way.</p> <p>24 Q How about in a review article of all the</p> <p>25 literature, is it appropriate to cherry-pick in</p>	<p style="text-align: right;">Page 145</p> <p>1 nature of the review. Reviews aren't -- they're</p> <p>2 not black and white like that. You might have</p> <p>3 certain pieces of evidence that you need as</p> <p>4 supporting lines of evidence. In that case it</p> <p>5 might be appropriate to choose representative</p> <p>6 pieces of evidence.</p> <p>7 Certainly in -- in my work for CDC, we</p> <p>8 are often in the situation of having to choose the</p> <p>9 best available evidence as part of an evidence</p> <p>10 synthesis, and so that does involve choosing</p> <p>11 certain studies over other studies.</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q How about -- but I'm talking about a</p> <p>14 systematic and comprehensive review of the entire</p> <p>15 body of literature. Is it appropriate in that</p> <p>16 situation to cherry-pick?</p> <p>17 MR. TISI: Objection. Asked and</p> <p>18 answered.</p> <p>19 THE WITNESS: I think I did answer that</p> <p>20 question. I think it depends on -- on the</p> <p>21 context, the stated objective of the review, the</p> <p>22 topic of the review, the methods for the review,</p> <p>23 and the context of what you're accusing</p> <p>24 cherry-picking.</p> <p>25 BY MR. HEGARTY:</p>

<p style="text-align: right;">Page 146</p> <p>1 Q So it's your opinion then in some</p> <p>2 situations it's okay to cherry-pick --</p> <p>3 MR. TISI: Objection.</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q -- a systematic or comprehensive review?</p> <p>6 MR. TISI: Objection.</p> <p>7 THE WITNESS: No. Those aren't my</p> <p>8 words.</p> <p>9 BY MR. HEGARTY:</p> <p>10 Q You just said that --</p> <p>11 A That's not what I said.</p> <p>12 Q You just said that are instances -- you</p> <p>13 can't make the -- the -- a general statement that</p> <p>14 it's improper to cherry-pick in doing a systematic</p> <p>15 and comprehensive review.</p> <p>16 MR. TISI: Objection. "Cherry-picking"</p> <p>17 is your word, Counsel. It's not been hers, and</p> <p>18 she's been clear about that.</p> <p>19 MR. HEGARTY: Do you want to get into</p> <p>20 whether that's a proper objection, Chris?</p> <p>21 MR. TISI: It is -- it is a totally</p> <p>22 proper objection. She --</p> <p>23 MR. HEGARTY: You're to object --</p> <p>24 MR. TISI: She -- she --</p> <p>25 MR. HEGARTY: You're to object to form</p>	<p style="text-align: right;">Page 148</p> <p>1 for only talking about one part of a body of</p> <p>2 literature and not talking on the body of</p> <p>3 literature that shows something different, don't</p> <p>4 you?</p> <p>5 A Can you be more specific?</p> <p>6 Q Do you ever accuse Drs. Huncharek and</p> <p>7 Muscat in your meta- -- your report of</p> <p>8 cherry-picking -- not using that term, but of</p> <p>9 cherry-picking?</p> <p>10 A I believe I --</p> <p>11 MR. TISI: Objection.</p> <p>12 THE WITNESS: -- do provide examples</p> <p>13 where I feel like they haven't represented a</p> <p>14 balanced discussion of certain issues. I don't</p> <p>15 know if that's what you're referring to.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q Would you call that cherry-picking?</p> <p>18 A I said I don't use that word. I -- I</p> <p>19 just --</p> <p>20 Q Well, what do you call it?</p> <p>21 A An imbalanced or -- imbalanced</p> <p>22 discussion. Yeah.</p> <p>23 Q If an author in a publication has an</p> <p>24 imbalanced discussion, does that threaten the</p> <p>25 validity of the work?</p>
<p style="text-align: right;">Page 147</p> <p>1 from the court's rules.</p> <p>2 MR. TISI: You don't need to tell me --</p> <p>3 you don't need to tell me how to -- how to defend</p> <p>4 a deposition. You asked her about a definition.</p> <p>5 She disagreed with your concept, asked you to</p> <p>6 define it, and now you're -- now you're</p> <p>7 force-feeding her a word. So I'm objecting to</p> <p>8 your use of a word that she had a concern with.</p> <p>9 BY MR. HEGARTY:</p> <p>10 Q Well, let me ask it this way: Is it</p> <p>11 ever proper in a systematic and comprehensive</p> <p>12 review to only focus on one side of a particular</p> <p>13 issue where there -- there's data on the other</p> <p>14 side and not mention the data on the other side?</p> <p>15 MR. TISI: Objection.</p> <p>16 THE WITNESS: If -- it depends on the --</p> <p>17 again, it depends on the objective of the review.</p> <p>18 I don't know what you mean by one side or the</p> <p>19 other. Again, that would be contextually</p> <p>20 dependent. Is there even a one side or another</p> <p>21 depending on the research question?</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q Well, we'll get -- we'll get to this in</p> <p>24 a moment.</p> <p>25 You criticized Drs. Huncharek and Muscat</p>	<p style="text-align: right;">Page 149</p> <p>1 A It depends on what the stated objective</p> <p>2 study designs are.</p> <p>3 Q What if the intent of the study is to</p> <p>4 present a balanced review of the literature, but</p> <p>5 the author doesn't do a balanced review of the</p> <p>6 literature, does that threaten the validity of the</p> <p>7 work?</p> <p>8 A I think it depends on the nature of the</p> <p>9 imbalance within the context of that particular</p> <p>10 study. I mean a certain imbalance may not be a</p> <p>11 big threat to validity or a big risk of bias, so</p> <p>12 that may not carry as much weight as an imbalanced</p> <p>13 discussion of something that's a very prominent or</p> <p>14 central issue in that particular research</p> <p>15 question.</p> <p>16 Q All the things that you criticized the</p> <p>17 2003, 2007 and 2009 papers, according to you,</p> <p>18 render those works invalid and unreliable. Is</p> <p>19 that your opinion?</p> <p>20 A My opinion is that there are serious</p> <p>21 substantive errors and methodologic deficiencies</p> <p>22 in these papers that make them very unreliable or</p> <p>23 limit the validity of the studies.</p> <p>24 Q And those same standards should be</p> <p>25 applied to all the work done by the plaintiffs'</p>

<p style="text-align: right;">Page 150</p> <p>1 experts in this litigation, correct?</p> <p>2 MR. TISI: Objection.</p> <p>3 THE WITNESS: Can you repeat the</p> <p>4 question?</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q Sure. The standards that you apply in</p> <p>7 your report about doing proper analysis and</p> <p>8 studies and publications should be applied to all</p> <p>9 the plaintiffs' experts' reports in this case,</p> <p>10 correct?</p> <p>11 MR. TISI: Objection.</p> <p>12 THE WITNESS: Well, again, I don't think</p> <p>13 I specified any particular standards. I think</p> <p>14 that I said it's contextually dependent upon what</p> <p>15 the objected -- objective is, what the study</p> <p>16 design is, what the questions are, and so on.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q So you don't cite in your report any</p> <p>19 objective standards for evaluating a published</p> <p>20 work, correct?</p> <p>21 A I -- I don't recall what I cited.</p> <p>22 Q Can you cite for me any objective</p> <p>23 standards for evaluating the validity and</p> <p>24 reliability of a work?</p> <p>25 A Again, I think I did talk about textbook</p>	<p style="text-align: right;">Page 152</p> <p>1 we're bouncing between concepts. If you're</p> <p>2 talking about an assessment of the internal</p> <p>3 validity of an epidemiologic study, then I just</p> <p>4 described what that entails.</p> <p>5 Q Well, we'll come back to it.</p> <p>6 Now, you state it calls -- in your</p> <p>7 report that you found superficial and substantive</p> <p>8 errors, methodological concerns, and lack of</p> <p>9 transparency that you say call into question the</p> <p>10 accuracy, validity and reliability of the works</p> <p>11 you looked at from Drs. Huncharek and Muscat.</p> <p>12 And does that mean that, according to</p> <p>13 your standards, work that has superficial and</p> <p>14 substantive errors calls into question the</p> <p>15 accuracy, validity and reliability of the work?</p> <p>16 A Again, it's going to be the same answer.</p> <p>17 It's dependent upon what the stated objective of a</p> <p>18 study was, what the intended use is, what the</p> <p>19 conclusions were. You can't take an evaluation</p> <p>20 out of context.</p> <p>21 Q Well, how many superficial errors in a</p> <p>22 published work is okay?</p> <p>23 A I think that depends on the nature of</p> <p>24 the errors and how significant they are, what the</p> <p>25 impact of those errors are.</p>
<p style="text-align: right;">Page 151</p> <p>1 epidemiology in terms of internal validity. The</p> <p>2 evaluation of internal validity. Right. That</p> <p>3 gets to the reliability, the validity of the</p> <p>4 measurement, the risk of bias, the extent to which</p> <p>5 it's being controlled for, all textbook</p> <p>6 epidemiology.</p> <p>7 Q And those standards should be applied to</p> <p>8 the plaintiffs' experts' reports in the MDL</p> <p>9 cases -- the MDL case, correct?</p> <p>10 MR. TISI: Objection.</p> <p>11 THE WITNESS: I don't know what the</p> <p>12 plaintiffs' experts' reports were or what they</p> <p>13 were charged with, so I can't -- I can't answer</p> <p>14 that.</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q It should be applied to the work you did</p> <p>17 in your report, though, correct?</p> <p>18 A Well, my report was a critical review of</p> <p>19 a very specific body of evidence.</p> <p>20 Q And the objective standards that are in</p> <p>21 the published literature should be applied to your</p> <p>22 work, correct?</p> <p>23 A Again, just to make sure we're talking</p> <p>24 about the same thing, we're talking about an</p> <p>25 assessment of the internal validity. I feel like</p>	<p style="text-align: right;">Page 153</p> <p>1 Q And how many substantive errors are</p> <p>2 okay?</p> <p>3 A Again, that's a critical evaluation</p> <p>4 that's contextually dependent.</p> <p>5 Q And where are all of these contextually</p> <p>6 dependent standards set out in the published</p> <p>7 literature?</p> <p>8 A This is expert, right, review and</p> <p>9 textbook epidemiology. This is scientific</p> <p>10 standards.</p> <p>11 Q Well, just cite for me the text or</p> <p>12 authority that says that the number of superficial</p> <p>13 errors, the number of substantive errors is all</p> <p>14 contextual and depends on the -- the stated</p> <p>15 objectives, et cetera. Cite for me a work that</p> <p>16 says that.</p> <p>17 A I can't as I sit here. That doesn't</p> <p>18 mean it doesn't exist. I think it's -- I think I</p> <p>19 did cite some of the references to scientific</p> <p>20 integrity that get at what you're talking about.</p> <p>21 Q Well, in the end, your report is your</p> <p>22 subjective take on these studies, correct?</p> <p>23 A My report represents my expert review of</p> <p>24 these studies. Correct.</p> <p>25 Q Well, you don't employ any type of</p>

<p style="text-align: right;">Page 154</p> <p>1 objective published scoring system, correct?</p> <p>2 MR. TISI: Objection.</p> <p>3 THE WITNESS: That -- that's correct.</p> <p>4 I -- I wouldn't do that.</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q You don't speak for any --</p> <p>7 A That would be --</p> <p>8 Q I'm sorry.</p> <p>9 A No, that's okay.</p> <p>10 THE REPORTER: I'm sorry --</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q You don't speak for any scientific</p> <p>13 group, correct?</p> <p>14 MR. TISI: Objection.</p> <p>15 THE WITNESS: Correct.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q You don't speak for any -- epidemiologic</p> <p>18 group or entity for purposes of your report, do</p> <p>19 you?</p> <p>20 A Correct.</p> <p>21 Q Or any journal, correct?</p> <p>22 A Correct.</p> <p>23 Q You haven't provided your critique to</p> <p>24 any of the journals that have published these</p> <p>25 papers, correct?</p>	<p style="text-align: right;">Page 156</p> <p>1 Q In the end, you're speaking only for</p> <p>2 yourself as part of your report, correct?</p> <p>3 A I am speaking for myself as a scientist</p> <p>4 and a public health researcher, that's correct.</p> <p>5 Q And -- and as an expert paid by the</p> <p>6 plaintiffs in this case, correct?</p> <p>7 A That is correct.</p> <p>8 Q That's also a title of yours, right?</p> <p>9 You're a paid plaintiffs' expert in this</p> <p>10 litigation, right?</p> <p>11 MR. TISI: Objection.</p> <p>12 THE WITNESS: If you want to -- if you</p> <p>13 want to give me that title, that's fine. I</p> <p>14 don't -- that's not a title I walk around using.</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q But you're being paid to testify and to</p> <p>17 write your report, correct?</p> <p>18 A I am a consultant. I do get paid by</p> <p>19 people. 75 percent is industry.</p> <p>20 Q I'm talking about for purposes of</p> <p>21 litigation, you were paid -- you've been paid for</p> <p>22 your work, correct?</p> <p>23 A Sure. Absolutely, yes.</p> <p>24 Q And you're testifying for the plaintiffs</p> <p>25 in this case, correct?</p>
<p style="text-align: right;">Page 155</p> <p>1 A Well, I -- I have initiated that</p> <p>2 process. I have not done it yet.</p> <p>3 Q Okay. You haven't communicated with</p> <p>4 these journals and advised them of the critiques</p> <p>5 that you have set out in your report, correct?</p> <p>6 A I have generally advised them of -- of</p> <p>7 the issues.</p> <p>8 Q And those are set out in the e-mails</p> <p>9 that we marked earlier.</p> <p>10 A Correct.</p> <p>11 Q You haven't provided your critique of</p> <p>12 these studies to FDA, correct?</p> <p>13 A Correct.</p> <p>14 Q No journal or entity has said the things</p> <p>15 you have stated in your report, correct?</p> <p>16 A I don't -- I don't know whether that's</p> <p>17 true or not.</p> <p>18 Q Can you cite anyone outside of this</p> <p>19 litigation who has said the things you are saying</p> <p>20 about these publications in your report?</p> <p>21 A I don't know.</p> <p>22 Q Can you cite anyone outside of the</p> <p>23 litigation that has said the things you are saying</p> <p>24 about the 2009 response to the citizen petition?</p> <p>25 A I don't know if that exists or not.</p>	<p style="text-align: right;">Page 157</p> <p>1 A That is correct.</p> <p>2 Q The 2003, 2007 articles were peer</p> <p>3 reviewed, correct?</p> <p>4 A That's correct.</p> <p>5 Q Your report has not been peer reviewed,</p> <p>6 right?</p> <p>7 A Not yet.</p> <p>8 Q The 2003 and 2007 papers were published</p> <p>9 in journals, correct?</p> <p>10 A That's correct.</p> <p>11 Q Your report has never been published in</p> <p>12 a journal, correct?</p> <p>13 A Correct.</p> <p>14 Q In the "Assignment" section in your</p> <p>15 report on page 6, at the bottom before the</p> <p>16 "Summary of Opinions," you say that you were asked</p> <p>17 to address the methodology of the 2009 Huncharek</p> <p>18 and Muscat, H&M reports, reports submitted to the</p> <p>19 FDA in a subsequent 2011 publication, correct?</p> <p>20 A Yes, that's correct.</p> <p>21 Q Who gave you this assignment?</p> <p>22 A The plaintiff lawyers.</p> <p>23 Q Did they give you an assignment that you</p> <p>24 didn't do or didn't have time to do?</p> <p>25 A No.</p>

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<p style="text-align: right;">Page 158</p> <p>1 Q In that same paragraph, you state that</p> <p>2 the 2011 publications -- you say that the report</p> <p>3 in the 2011 publication were on behalf of the</p> <p>4 talcum powder industry to FDA.</p> <p>5 A Correct.</p> <p>6 Q What is the authority you have for</p> <p>7 saying that the authors published the 2011 article</p> <p>8 on behalf of the talcum powder industry?</p> <p>9 A My understanding is that they were</p> <p>10 consultants of the industry at the time and also</p> <p>11 litigation experts.</p> <p>12 Q And is that the only basis you have for</p> <p>13 saying that that article was published on behalf</p> <p>14 of the talcum powder industry?</p> <p>15 A Well, are you speaking about the 2011</p> <p>16 paper?</p> <p>17 Q Yes.</p> <p>18 A So my understanding is that over time,</p> <p>19 there was a chain of -- of relationship between</p> <p>20 the authors and the work that originated in 2000,</p> <p>21 and then showed up periodically over time in these</p> <p>22 various publications. So the data in the orig- --</p> <p>23 in the 2011 paper actually originated in -- in a</p> <p>24 2000 report.</p> <p>25 Q And what is the source of that</p>	<p style="text-align: right;">Page 160</p> <p>1 been peer reviewed. Have you submitted it for</p> <p>2 publication?</p> <p>3 A No, I have not.</p> <p>4 Q Why did you say not yet?</p> <p>5 A Because I intend to -- to submit the</p> <p>6 contents of it in some form.</p> <p>7 Q Okay. You intend to submit to who?</p> <p>8 A I'm -- a journal. I'm not sure yet.</p> <p>9 Q In what form?</p> <p>10 A I'm not sure yet.</p> <p>11 THE WITNESS: I really hate to do this.</p> <p>12 I have to run to the bathroom.</p> <p>13 MR. HEGARTY: Okay.</p> <p>14 THE WITNESS: But, I mean, I can</p> <p>15 literally be like three minutes.</p> <p>16 MR. HEGARTY: Okay. Go off the record.</p> <p>17 THE VIDEOGRAPHER: The time is 11:59</p> <p>18 a.m. We're going off the record.</p> <p>19 (Recess.)</p> <p>20 THE VIDEOGRAPHER: The time is</p> <p>21 12:04 p.m. We're back on the record.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q Okay, Doctor, we left off talking about</p> <p>24 the "Summary of Opinions" section on pages 6 and</p> <p>25 7. In this section you state that -- at the top</p>
<p style="text-align: right;">Page 159</p> <p>1 understanding?</p> <p>2 A The documents, the proposal to J&J and</p> <p>3 the preliminary data report.</p> <p>4 Q In the section "Summary of Opinions"</p> <p>5 at the bottom of page 6, carrying over to the top</p> <p>6 of page 7, you say: "The 2003 and 2007 papers</p> <p>7 did not utilize generally accepted methodologies</p> <p>8 and best practices in epidemiology and</p> <p>9 meta-analysis."</p> <p>10 A Correct.</p> <p>11 Q Where are these methodologies and best</p> <p>12 practices published?</p> <p>13 A So again, I would refer you to the</p> <p>14 Cochrane Collaboration. They have a handbook on</p> <p>15 meta-analysis. There are other resources as well.</p> <p>16 There's textbooks on meta-analysis. Borenstein is</p> <p>17 one.</p> <p>18 Q Okay. You have never published a paper</p> <p>19 on methodologies and best practices in</p> <p>20 epidemiology, correct?</p> <p>21 A I don't -- no, I haven't had a published</p> <p>22 paper that was specifically aimed at that</p> <p>23 objective.</p> <p>24 Q Going back to something you mentioned a</p> <p>25 moment ago, you said that your MDL report has not</p>	<p style="text-align: right;">Page 161</p> <p>1 of page 7, you state that these studies were</p> <p>2 heavily relied on by the talc industry in the</p> <p>3 2000 -- in its 2009 submission.</p> <p>4 Do you see where I'm reading?</p> <p>5 A I do.</p> <p>6 Q You also state at the bottom of page 8</p> <p>7 that these studies were a primary focus of the</p> <p>8 arguments advanced by the talc industry in</p> <p>9 opposition to a mandatory cancer warning on talcum</p> <p>10 powder products.</p> <p>11 Do you see that?</p> <p>12 A I do.</p> <p>13 Q What is your basis for saying that the</p> <p>14 talc industry heavily relied on the 2003 and 2007</p> <p>15 studies?</p> <p>16 A The basis is the -- the PCPC report in</p> <p>17 which Huncharek and Muscat elevate their studies</p> <p>18 and emphasize their studies, sometimes not</p> <p>19 discussing the fullness of the literature on the</p> <p>20 topic, but raising their studies as important</p> <p>21 pieces of evidence on important lines of evidence</p> <p>22 related to causation.</p> <p>23 Q And did you -- is there some objective</p> <p>24 standard that you applied to come up with the</p> <p>25 phrase "heavily relied on"?</p>

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<p>1 A Well, I did note that they cited their 2 own studies over 25 times. 3 Q Do you say that in your report? 4 A No, it's not in my report. It's just 5 something I noted during my review. 6 Q Is there a published objective 7 standard that defines objective -- that assigns 8 heavily reliance based on the number of times -- 9 MR. TISI: Objection. 10 BY MR. HEGARTY: 11 Q -- a paper is cited in a journal or a 12 publication? 13 MR. TISI: Objection. 14 THE WITNESS: I'm not aware that 15 something like that would exist. Certainly this 16 falls under my purview in terms of my critical 17 analysis of these papers. 18 BY MR. HEGARTY: 19 Q Well, what is the basis for your saying 20 that the -- these studies were the primary 21 focus -- what's the objective standard for 22 defining "primary focus"? 23 MR. TISI: Objection. 24 THE WITNESS: I think I just answered 25 the question. The emphasis on the studies,</p>	<p>1 THE WITNESS: That's not a thing, to my 2 knowledge. So I don't know that that would exist. 3 Again, I think this just falls within the purview 4 of a critical review. 5 BY MR. HEGARTY: 6 Q When have you ever before in a published 7 article used the phrase "primary focus" or "heavy 8 reliance"? 9 A I -- I don't know. I don't recall every 10 word of everything I've ever written. 11 Q On -- also on page 7 at the very last 12 line, you say that: "Any scientific, regulatory 13 or policy deliberation or decisions, including but 14 not limited to those undertaken and issued by FDA 15 that relied upon the data and analysis put forward 16 by Drs. Huncharek and Muscat, in whole or in part, 17 are based on flawed data, calculations and 18 conclusions." 19 Do you see where I'm reading? 20 A I do. 21 Q First of all, are you saying that 22 everything in the 2009 submission was flawed? 23 MR. TISI: Objection. 24 THE WITNESS: I'm not saying that 25 everything in the 2009 submission was flawed. I</p>
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<p>1 sometimes at the cost of other studies, and the 2 fullness of the literature and data that's 3 available on a particular topic. 4 BY MR. HEGARTY: 5 Q What published standards did you apply 6 that defines "heavy reliance"? 7 MR. TISI: Objection. Asked and 8 answered. 9 THE WITNESS: I think I answered that 10 question. 11 BY MR. HEGARTY: 12 Q Well, it's your subjective take on 13 the -- the -- 14 A Well, it's -- sure. 15 MR. TISI: Objection. 16 THE WITNESS: It's my expert review, 17 yes. Correct. 18 BY MR. HEGARTY: 19 Q And I'm asking you, can you cite for me 20 any published authorities that -- that sets forth 21 the standard for looking at a publication and 22 defining what you have to show to say there's 23 heavy reliance and there's primary focus on these 24 studies? 25 MR. TISI: Objection.</p>	<p>1 think I'm saying just what I wrote in my report. 2 BY MR. HEGARTY: 3 Q Are you saying that every discussion of 4 the studies that are set out in the response 5 are -- is flawed? 6 MR. TISI: Objection. 7 THE WITNESS: I'm not sure what you're 8 asking me. 9 BY MR. HEGARTY: 10 Q Well, there are a number of discussions 11 in the beginning of the response to publications, 12 and many of which you don't refer to. 13 Are all the discussions about the 14 publications that were cited in the citizen 15 petition flawed by Drs. Huncharek and Muscat? 16 MR. TISI: Objection. 17 THE WITNESS: I'm not saying that. That 18 wasn't the focus of -- of my review. 19 BY MR. HEGARTY: 20 Q Is it your opinion that none of the 21 statements in the response were supported by the 22 studies and data referenced? 23 A That is not my opinion. That's not what 24 I'm saying. 25 Q Your report in the end is limited to the</p>

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<p>1 data and conclusions you list from the 2003, the</p> <p>2 2007 and 2009 response, correct?</p> <p>3 A Can you repeat that, please?</p> <p>4 Q Sure.</p> <p>5 Your report about the problems you found</p> <p>6 with the 2003, 2007, 2009 documents are those that</p> <p>7 you set out in your report, correct?</p> <p>8 MR. TISI: Objection. Asked and</p> <p>9 answered.</p> <p>10 THE WITNESS: I think -- I think in</p> <p>11 general, yes, I've laid that out. I think as I've</p> <p>12 explained it, it's data that began and was</p> <p>13 originated in 2000, and was propagated and</p> <p>14 disseminated over a period of time in -- in these</p> <p>15 various -- various publications.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q You agree that not everything in the</p> <p>18 2003, the 2007 and 2009 papers is inaccurate.</p> <p>19 MR. TISI: Objection.</p> <p>20 THE WITNESS: I certainly -- I certainly</p> <p>21 agree with regard to -- I don't know what -- can</p> <p>22 you rephrase, please? I don't know what --</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q Sure.</p> <p>25 Do you agree that not everything in the</p>	<p>1 statement in the paper. I was focused on the</p> <p>2 critical scientific and epidemiologic issues.</p> <p>3 Q Do you intend to testify that PCPC and</p> <p>4 J&J or Imerys intended to present flawed data to</p> <p>5 the FDA?</p> <p>6 MR. TISI: Objection. Asked and</p> <p>7 answered.</p> <p>8 THE WITNESS: I'm not testifying to</p> <p>9 intent.</p> <p>10 BY MR. HEGARTY:</p> <p>11 Q Is it your contention that the FDA</p> <p>12 relied on the 2003 and 2007 papers in making</p> <p>13 decisions about talc and ovarian cancer for the</p> <p>14 citizen petitions?</p> <p>15 A It -- it is my -- I'm sorry, what word</p> <p>16 did you use?</p> <p>17 Q Yeah, is it your contention that FDA</p> <p>18 relied on the 2003 and 2007 papers in making</p> <p>19 decisions about talc and ovarian cancer for the</p> <p>20 citizen petitions?</p> <p>21 A So I would say, yes, on the basis of FDA</p> <p>22 citing that they -- in their denial letter, excuse</p> <p>23 me, that they reviewed and considered all of the</p> <p>24 data that was submitted in support of the work --</p> <p>25 surrounding, I should say, the citizen petitions.</p>
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<p>1 2003, 2007 and 2009 documents you discuss in your</p> <p>2 report is inaccurate?</p> <p>3 MR. TISI: Are you talking about the</p> <p>4 data, or what are you talking about?</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q Can you answer the question?</p> <p>7 MR. TISI: Well, objection. Vague.</p> <p>8 THE WITNESS: I don't know what</p> <p>9 "everything" means.</p> <p>10 BY MR. HEGARTY:</p> <p>11 Q Well, is every sentence, every data</p> <p>12 cite -- or strike that.</p> <p>13 Do you agree that not every sentence,</p> <p>14 not every data cite, not every reference to data</p> <p>15 is inaccurate in the 2003, 2007, and 2009 papers,</p> <p>16 right?</p> <p>17 MR. TISI: Objection. Beyond the scope.</p> <p>18 THE WITNESS: Sure, there are words that</p> <p>19 are spelled correctly. There are proper cites.</p> <p>20 There are proper numbers.</p> <p>21 BY MR. HEGARTY:</p> <p>22 Q There are statements that are not</p> <p>23 inaccurate?</p> <p>24 A I'm sure that there are. I didn't -- I</p> <p>25 didn't do just a blanket analysis of every</p>	<p>1 Q Well, what data do you have that FDA</p> <p>2 actually relied on the 2003 and 2007 papers in</p> <p>3 responding to the citizen petition?</p> <p>4 A The denial letter that that data was</p> <p>5 part of their review.</p> <p>6 Q Did they refer to the 2003 and 2007</p> <p>7 papers in the denial letter?</p> <p>8 A I don't recall. But I think -- the</p> <p>9 language I'm recalling is that we have -- well, we</p> <p>10 could pull it up actually. That might be better.</p> <p>11 Q Well, I will. We'll get to that.</p> <p>12 But -- okay. Who at FDA relied on the</p> <p>13 2003 and 2007 papers --</p> <p>14 MR. TISI: Objection.</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q -- as to the citizen petition?</p> <p>17 MR. TISI: I'm sorry.</p> <p>18 THE WITNESS: I can't answer that kind</p> <p>19 of question.</p> <p>20 MR. TISI: I'm sorry. I need to place</p> <p>21 an objection. Asked and answered.</p> <p>22 THE WITNESS: Sorry.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q Well, what person or persons relied on</p> <p>25 the 2003 and 2007 papers --</p>

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<p>1 MR. TISI: Objection.</p> <p>2 BY MR. HEGARTY:</p> <p>3 Q -- at FDA?</p> <p>4 MR. TISI: Objection. Asked and</p> <p>5 answered.</p> <p>6 THE WITNESS: I can't answer that</p> <p>7 because I don't know the inner workings of who</p> <p>8 reviewed what as part of that.</p> <p>9 BY MR. HEGARTY:</p> <p>10 Q Well, at what point in time during the</p> <p>11 review process did they rely on the 2003 and 2007</p> <p>12 papers?</p> <p>13 A I don't know. You would have to ask</p> <p>14 them.</p> <p>15 Q On which part of the papers did they</p> <p>16 rely upon for purposes of the -- the review of the</p> <p>17 2008 and 2000 -- 1994 citizen petitions?</p> <p>18 A I -- I can't answer specifically what --</p> <p>19 what specific parts they relied on per se. What</p> <p>20 I -- what I can say, however, is that a lot of the</p> <p>21 language and arguments and positions that were</p> <p>22 proffered in the PCPC reports are echoed in FDA's</p> <p>23 denial letter. So it does -- it does seem to me</p> <p>24 eerily similar and indicative to me in my opinion</p> <p>25 that they considered that data.</p>	<p>1 petitions?</p> <p>2 A Actually, can you go back and repeat the</p> <p>3 prior question? I'm sorry.</p> <p>4 Q Well, the question was, do you have any</p> <p>5 other basis for saying that FDA relied on the 2003</p> <p>6 and 2007 papers in making decisions about talc and</p> <p>7 ovarian cancer other than the 2014 citizen --</p> <p>8 denial and citizen petition?</p> <p>9 A Other than knowing that that was part of</p> <p>10 what they considered in their analysis, I can't</p> <p>11 say for sure how much weight they gave -- gave to</p> <p>12 those.</p> <p>13 Q Do you even know if they reviewed the</p> <p>14 2003 and 2007 papers?</p> <p>15 A I would assume so. I would hope so</p> <p>16 based on their statements that they considered all</p> <p>17 of the data submitted. And I think actually they</p> <p>18 do cite to one of the studies on the docket</p> <p>19 online. I do believe that they list one -- at</p> <p>20 least one of the studies there.</p> <p>21 Q Do you know -- do you know if the</p> <p>22 totality of the 2003 and 2007 papers, all the</p> <p>23 papers themselves were submitted as part of the --</p> <p>24 the papers submitted as part of the review</p> <p>25 process?</p>
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<p>1 Q Well, what weight did individuals at FDA</p> <p>2 in reviewing the 2003 and 2007 petition -- strike</p> <p>3 that.</p> <p>4 What weight did the FDA give to the 2003</p> <p>5 and 2007 papers in their review of the citizen</p> <p>6 petitions?</p> <p>7 A I can't answer that.</p> <p>8 Q What was the extent or nature of the</p> <p>9 reliance that they -- that they -- that they gave</p> <p>10 to those papers?</p> <p>11 A Again, they're not very detailed in the</p> <p>12 denial letter about what their process was</p> <p>13 exactly, so I can't answer that.</p> <p>14 Q What else did they rely on outside of</p> <p>15 what's reported in the denial letter?</p> <p>16 A I -- I can't be certain of -- again,</p> <p>17 because of -- of lack of detail in their methods</p> <p>18 and process, I can't be sure of what they relied</p> <p>19 on.</p> <p>20 Q Do you have any basis to say that FDA</p> <p>21 relied on the 2003 and 2007 papers besides the</p> <p>22 2014 denial letter?</p> <p>23 A No, I don't.</p> <p>24 Q Do you have any personal knowledge of</p> <p>25 how FDA evaluated the 1994 and 2008 citizen</p>	<p>1 A Well, there's -- certainly the data is</p> <p>2 reviewed and referenced within the PCPC report.</p> <p>3 Q Do you know if FDA read, actually read,</p> <p>4 the 2003 and 2007 papers you reference in your</p> <p>5 report?</p> <p>6 A Again, I -- I -- no, I can't know that.</p> <p>7 Q You did review, as we just talked about,</p> <p>8 the FDA's April 2014 denial letter of the citizen</p> <p>9 petitions, correct?</p> <p>10 A Correct.</p> <p>11 MR. HEGARTY: I'll mark as Exhibit</p> <p>12 No. 12 that denial letter.</p> <p>13 (Zambelli-Weiner Exhibit No. 12</p> <p>14 was marked for identification.)</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q You've seen the denial letter, correct?</p> <p>17 A Yes.</p> <p>18 Q You agree that nowhere FDA cited in its</p> <p>19 analysis to either the 2003 or 2007 studies,</p> <p>20 correct?</p> <p>21 A Again, can you just give me a minute to</p> <p>22 look at this?</p> <p>23 Q How much time do you need?</p> <p>24 A Just a few minutes.</p> <p>25 MR. HEGARTY: Let's go off the record.</p>

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<p style="text-align: right;">Page 174</p> <p>1 MR. TISI: No, we're not going to go off 2 the record. She's just -- she's just looking at 3 the document. 4 MR. HEGARTY: If she needs a few 5 minutes, we're going to go off the record. 6 THE VIDEOGRAPHER: Off -- 7 MR. HEGARTY: Yeah, go -- well, yeah, go 8 off the record. 9 THE VIDEOGRAPHER: The time is 10 12:17 p.m. We're going off the record. 11 (Pause.) 12 THE VIDEOGRAPHER: The time is 13 12:17 p.m. We're back on the record. 14 BY MR. HEGARTY: 15 Q Going back to my question, Doctor, 16 nowhere in the 2014 letter did FDA cite to either 17 the 2003 or 2007 studies, correct? 18 A So they don't cite directly to the two 19 studies, but they do say that they have reviewed 20 the comments received in response to the 21 petitions, which are obviously inclusive of the 22 2003 and 2007 data contained within that report. 23 And as I also said, there may -- it may be listed 24 as a reference on the docket as well. 25 Q Let me see if I can get an answer to my</p>	<p style="text-align: right;">Page 176</p> <p>1 for asbestos. Do you see that, at the top of the 2 page? 3 A Just the first paragraph, is that 4 what you're -- 5 Q The first two paragraphs. 6 A First two paragraphs. Okay. 7 Q Do you see where FDA cites to testing 8 for -- of talc for asbestos? 9 A They conducted an exploratory survey, is 10 that what you're referring to? 11 Q Yes. 12 A Yes. 13 Q That was not in the 2009 submission, 14 correct? 15 A Are you referring to the 2009 PCPC 16 report? 17 Q Yes. 18 A I wouldn't think so. That was a PCPC 19 report, and this is an FDA-sponsored survey. 20 Q The FDA's survey looking at asbestos in 21 talc was not in the 2003 or 2007 papers, correct? 22 A That's correct. 23 Q FDA also cited on page 3 under 24 "Toxicological Findings" to the 1993 NTP study. 25 That was not in the PCPC submission, was it?</p>
<p style="text-align: right;">Page 175</p> <p>1 question. 2 Did the FDA -- 3 MR. TISI: She answered. 4 BY MR. HEGARTY: 5 Q -- anywhere in its letter cite to the 6 2003 or 2007 studies you reference in your report? 7 A I answered you. I led with that answer. 8 I said they do not directly cite to the 2003 and 9 2007 papers. 10 Q Nowhere did FDA cite to the 2009 11 submission by PCPC, correct? They don't refer to 12 it by name, do they? 13 A Well -- 14 MR. TISI: Objection, Counsel. 15 THE WITNESS: -- as the only comment 16 submitted in response to the citizen petition, 17 it's implied. 18 BY MR. HEGARTY: 19 Q But do they actually include a cite 20 anywhere to the 2009 submission by PCPC? 21 A They don't directly call out the 22 2009 PCPC report, at least as far as I recall, but 23 we can look at this more if you want. 24 Q If you turn to page 3 of the FDA's 25 letter, FDA cites on that page its testing of talc</p>	<p style="text-align: right;">Page 177</p> <p>1 A I don't know if -- if the PCPC report 2 cites NTP. 3 Q Do you have that PCPC report with you? 4 A I do. 5 Q Can you cite -- can you find anywhere 6 where the PCP response -- PCPC response by 7 Drs. Huncharek and Muscat cite to the 1993 NTP 8 study? 9 A It's a little lengthy. You want me to 10 look? 11 Q Well, sitting here today, do you recall 12 it was cited? 13 A I don't recall if it was cited or not. 14 Q Okay. 15 A But, I mean, FDA does say on the first 16 page that they considered other scientific 17 information as well. So... 18 Q If you turn over to page 4, in the 19 paragraph before "Epidemiology and Etiology 20 Findings," the FDA states that it reviewed 15 21 articles from 1980 to 2008 not cited in the 22 petition. None of these would have been in the 23 2003 and 2007 articles by Drs. Huncharek and or 24 Dr. Huncharek and Muscat, correct? 25 A I don't know. Their language is cited</p>

45 (Pages 174 to 177)

<p style="text-align: right;">Page 178</p> <p>1 in your petitions. So I don't know what that</p> <p>2 implies.</p> <p>3 Q Did the 2009 submission by the PCPC have</p> <p>4 15 articles from 1980 to 2008 on toxicology?</p> <p>5 A I don't recall.</p> <p>6 Q FDA stated also on page 4 that it</p> <p>7 considered the scientific literature submitted in</p> <p>8 support of both citizen petitions. That would</p> <p>9 include Huncharek's 2003 study, as well as 11</p> <p>10 other pieces of literature not authored by</p> <p>11 Dr. Huncharek or Dr. Muscat. Correct?</p> <p>12 A Can you repeat that? That was long.</p> <p>13 Q Sure.</p> <p>14 The FDA says on that page that it</p> <p>15 reviewed the literature submitted in support of</p> <p>16 both citizen petitions, correct? That's at the</p> <p>17 bottom -- I'm sorry, in the middle of the page.</p> <p>18 A Under "Epidemiology and Etiology" --</p> <p>19 Q Yes, second paragraph.</p> <p>20 A After consideration of the scientific</p> <p>21 literature, yes.</p> <p>22 Q So they did submit the literature the</p> <p>23 citizen -- the citizen petition provided, correct?</p> <p>24 A Correct.</p> <p>25 Q Do you agree that FDA reviewed far more</p>	<p style="text-align: right;">Page 180</p> <p>1 Q Is it your contention that any decision</p> <p>2 by FDA with regard to talc and ovarian cancer as</p> <p>3 to the citizen petitions would have been different</p> <p>4 if not for what you call is flawed data,</p> <p>5 calculations and conclusions in the 2003 and 2007</p> <p>6 study and 2009 submission?</p> <p>7 A Excuse me. Sorry. I apologize. Please</p> <p>8 repeat the question.</p> <p>9 Q Sure.</p> <p>10 Is it your contention that any decision</p> <p>11 by FDA with regard to talc and ovarian cancer in</p> <p>12 response to the citizen petitions would have been</p> <p>13 different if not for what you call the flawed</p> <p>14 data, calculations and conclusions in the 2003 and</p> <p>15 2007 studies and 2009 submission?</p> <p>16 A I can't say that any particular outcome</p> <p>17 would have been different, especially for FDA,</p> <p>18 because I don't know exactly what they did and how</p> <p>19 they weighed the evidence.</p> <p>20 That said, what I'm saying is if an</p> <p>21 analysis utilized the data and weighed it</p> <p>22 significantly, particularly for particular pieces</p> <p>23 of data, then that process is relying on flawed</p> <p>24 data.</p> <p>25 Q What has FDA reviewed about talc and</p>
<p style="text-align: right;">Page 179</p> <p>1 material than the 2003 and 2007 studies than</p> <p>2 what's cited in the 2009 response, correct?</p> <p>3 MR. TISI: Objection to the term "far</p> <p>4 more."</p> <p>5 THE WITNESS: Again, I -- I can't say</p> <p>6 what exactly they reviewed and what weight they</p> <p>7 gave to any particular piece of evidence, because</p> <p>8 of the lack of detail in -- in the letter.</p> <p>9 BY MR. HEGARTY:</p> <p>10 Q Can you cite for me any other -- strike</p> <p>11 that.</p> <p>12 Besides the FDA, can you cite for me any</p> <p>13 scientific, regulatory or policy decision or</p> <p>14 deliberation that as part of it reviewed and</p> <p>15 relied on the 2003 and 2007 studies?</p> <p>16 A I mean, certainly I know there are</p> <p>17 others. I would have to go back and review to --</p> <p>18 to recall whether they cited these studies or not.</p> <p>19 Q Well, can you cite for me any regulatory</p> <p>20 body who reviewed the 2003 and 2007 studies as</p> <p>21 part of any decision concerning talc and ovarian</p> <p>22 cancer?</p> <p>23 A That sounds like the same question to</p> <p>24 me. Again, not as I sit here, but I don't know</p> <p>25 that they didn't.</p>	<p style="text-align: right;">Page 181</p> <p>1 ovarian cancer since 2014?</p> <p>2 A I'm not sure as I sit here.</p> <p>3 Q Can you cite any other regulatory or</p> <p>4 policy decision maker who relied on the 2003 to</p> <p>5 2007 or the 2009 submission with regard to</p> <p>6 decisions or deliberations as to talc and ovarian</p> <p>7 cancer?</p> <p>8 A Again, I know Health Canada just came</p> <p>9 out with a draft assessment. I don't know if they</p> <p>10 cited these studies. I can't speak to what other</p> <p>11 agencies have cited these studies, and to what</p> <p>12 extent they've weighed them or relied on them --</p> <p>13 Q Can you --</p> <p>14 A -- as I sit here right now.</p> <p>15 Q I'm sorry.</p> <p>16 Can you even cite to any regulatory or</p> <p>17 policy decision maker who even reviewed the 2003</p> <p>18 or 2007 or 2011 papers or the 2009 submission?</p> <p>19 A Again, that was really beyond my</p> <p>20 purview, so I -- I don't know as I sit here. I</p> <p>21 mean, certainly we could find out if we wanted to.</p> <p>22 Q Can you cite any person who was</p> <p>23 influenced by the 2003 or 2007 papers?</p> <p>24 MR. TISI: Objection.</p> <p>25 THE WITNESS: I can't cite a specific</p>

<p style="text-align: right;">Page 182</p> <p>1 person, no. 2 BY MR. HEGARTY: 3 Q Can you cite any specific person who was 4 influenced by the 2009 submission? 5 A No, I can't cite a specific person. No. 6 Q On page 9 of your report, second 7 paragraph, you make the statement that the 2003 8 and 2009 studies influenced important regulatory 9 and policy decisions. 10 Do you see that? 11 A I'm sorry, where are you? 12 Q Second paragraph, page 9, first 13 sentence. You say that -- you make reference to 14 the 2003 and 2007 studies, and you say that they 15 influenced important regulatory and policy 16 decisions. 17 Do you see that? 18 A You talk fast, and I'm having trouble -- 19 MR. TISI: Where are you? 20 THE WITNESS: -- catching up. 21 MR. TISI: I'm sorry. I don't see -- 22 BY MR. HEGARTY: 23 Q Well, on page -- the second paragraph, 24 page 9, first sentence, you refer to the 2003 and 25 2007 studies, and then you say they influence</p>	<p style="text-align: right;">Page 184</p> <p>1 A I -- I'm using "intent" in the way that 2 all scientists, researchers, anyone producing data 3 has the intent to influence decision-making. 4 That's why we do what we do. I assume they also 5 had that intent or why would they have submitted 6 it. 7 Q So you intend to testify to that; is 8 that correct? 9 A No, I'm not -- I'm not testifying to 10 that. I'm saying -- 11 Q You used the word "intent." 12 MR. TISI: Objection, Counsel. 13 MR. HEGARTY: So -- 14 MR. TISI: I think "intent" is very 15 different than what you're using it now. 16 Go ahead and answer if there's a pending 17 question. 18 BY MR. HEGARTY: 19 Q Do you intend to testify that J&J, 20 Imerys or PCPC submitted the 2009 submission or 21 referenced the 2003 or 2007 papers with the intent 22 to influence the FDA's decision as to the citizen 23 petitions? 24 A I would -- again, I want to clarify that 25 I'm not offering an opinion on intent. I'm taking</p>
<p style="text-align: right;">Page 183</p> <p>1 important regulatory and policy decisions. 2 Do you see that? 3 A Correct. 4 Q What regulatory and policy decisions 5 were influenced? 6 A I think as part of the evidence base 7 on -- on talc and ovarian cancer, they are 8 influencing the policy decisions that come out of 9 that analysis. 10 Q Okay. 11 A To the extent that they are -- are 12 relied upon. 13 Q Who did they influence, what persons? 14 A I can't name specific people. 15 Q What bodies were influenced? 16 A Again, I've already answered that. I -- 17 I don't know -- I know that they were submitted in 18 support of a regulatory submission, the citizens 19 petition. So they were submitted to a regulatory 20 agency -- the data was submitted by industry to 21 the regulatory agency with the intent to influence 22 the decision-making. 23 Q So you are going to testify that the 24 materials were intent -- were submitted with the 25 intent to influence the regulatory agencies.</p>	<p style="text-align: right;">Page 185</p> <p>1 the process at its -- at its face value, that by 2 nature of submitting a comment, you want to 3 contribute something to the process just by the 4 nature of doing that. Otherwise, there's no 5 reason to do it. 6 Q When did this influence, if at all -- if 7 it happened, happen? What point in time? 8 A Again, I'm using the word "contribute," 9 "weigh in." We could substitute any number of 10 verbs. But, again, by submitting the comment, 11 they are contributing to the process. 12 Q How much time did FDA spend reviewing 13 the 2009 submission? 14 A I can't answer that. 15 Q Did FDA find the errors and issues you 16 set out in your report when they reviewed the 2003 17 or 2007 papers or the 2009 response? 18 A I don't know if they did or didn't. 19 Q What would have been the result of 20 the -- of the citizen petition process without the 21 issues you raise in your report? 22 A I -- I can't answer that. Again, I 23 think we've been over this about the lack of 24 detail in terms of their process and how much 25 weight was given to particular pieces of evidence.</p>

<p style="text-align: right;">Page 186</p> <p>1 You'd have to ask them.</p> <p>2 Q Can you cite -- strike that.</p> <p>3 On page 9, before the "Methodology"</p> <p>4 section, you state that, in the last paragraph:</p> <p>5 "Because the articles were given prominence in</p> <p>6 regulatory proceedings and in a publication by the</p> <p>7 talc industry, I have been asked to review and</p> <p>8 assess the validity of data in claims put forward</p> <p>9 by Dr. Michael Huncharek and Dr. Joshua Muscat."</p> <p>10 Do you see that?</p> <p>11 A I do.</p> <p>12 Q You were asked to do this review by</p> <p>13 plaintiffs' lawyers, right?</p> <p>14 A Correct.</p> <p>15 Q So they were the ones telling you that</p> <p>16 these articles were given added prominence,</p> <p>17 correct?</p> <p>18 A No. That was my own assessment.</p> <p>19 Because industry obviously has an obligation to</p> <p>20 ensure the safety of their products and -- and</p> <p>21 submit data to FDA that's reliable and valid. And</p> <p>22 so when that data is the only data that's</p> <p>23 submitted in response to the citizen petitions, it</p> <p>24 clearly has a special place there in that -- in</p> <p>25 that review process.</p>	<p style="text-align: right;">Page 188</p> <p>1 A Correct.</p> <p>2 MR. TISI: Well, let's finish the</p> <p>3 sentence. I just want it for the record, finish</p> <p>4 the sentence, please, Counsel.</p> <p>5 MR. HEGARTY: Well, you can finish it if</p> <p>6 you want.</p> <p>7 MR. TISI: No, I --</p> <p>8 BY MR. HEGARTY:</p> <p>9 Q What do you mean by --</p> <p>10 MR. TISI: Then I will finish it right</p> <p>11 now because you're asking your question --</p> <p>12 MR. HEGARTY: No, you will not.</p> <p>13 MR. TISI: Well, you -- well, you can't</p> <p>14 just -- you can't just ask half a sentence. I</p> <p>15 want the record to be clear.</p> <p>16 MR. HEGARTY: It's part of the question.</p> <p>17 I'm -- it's part of the question.</p> <p>18 MR. TISI: It's not part -- it's not</p> <p>19 part of the -- well, but the sentence is a full</p> <p>20 sentence, Counsel.</p> <p>21 BY MR. HEGARTY:</p> <p>22 Q What, Doctor, do you mean --</p> <p>23 MR. TISI: It's one thing to cherry-pick</p> <p>24 sentences. It's another thing to cherry-pick</p> <p>25 phrases within a sentence.</p>
<p style="text-align: right;">Page 187</p> <p>1 Q What is the stand- -- a published</p> <p>2 standard for what constitutes added prominence?</p> <p>3 A That question doesn't make sense to me.</p> <p>4 Q Well, that's your subjective opinion,</p> <p>5 correct?</p> <p>6 A That -- that is my expert analysis, yes,</p> <p>7 that's correct.</p> <p>8 Q But there's no publication that defines</p> <p>9 what constitutes added prominence of a publication</p> <p>10 or article in regulatory proceedings, is there?</p> <p>11 A Not to my knowledge. I'm sure we could</p> <p>12 debate, and it is my opinion that as the only</p> <p>13 comment, it had added prominence, and that being</p> <p>14 repeatedly cited within the report gives it added</p> <p>15 prominence as well.</p> <p>16 Q You state in the second paragraph on</p> <p>17 page 9 that the 2003 and 2007 articles assumed --</p> <p>18 A I'm sorry, where are you?</p> <p>19 Q Second paragraph, page 9.</p> <p>20 A Okay.</p> <p>21 Q You say that: "The 2003 and 2007</p> <p>22 articles assumed added importance from a</p> <p>23 regulatory and policy perspective due to the</p> <p>24 authors attributing weight to them."</p> <p>25 Do you see where I'm reading?</p>	<p style="text-align: right;">Page 189</p> <p>1 MR. HEGARTY: Well, lawyers can</p> <p>2 cherry-pick; authors can't.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q Doctor, what do you mean --</p> <p>5 MR. TISI: Are you telling me you're</p> <p>6 cherry-picking?</p> <p>7 BY MR. HEGARTY:</p> <p>8 Q What do you mean by added -- "assumed</p> <p>9 added importance"? What does that mean?</p> <p>10 A Just by -- by nature of what was being</p> <p>11 submitted. Again, by the industry advocating for</p> <p>12 their interpretation of the data, their</p> <p>13 recommendations, the obligation of industry to</p> <p>14 ensure the safety of their products and to submit</p> <p>15 reliable data to the FDA, that by nature makes</p> <p>16 this data special in this process.</p> <p>17 Q Cite --</p> <p>18 A That is --</p> <p>19 Q I'm sorry.</p> <p>20 A That is what I mean by "added</p> <p>21 importance, weight, prominence." You can</p> <p>22 substitute adjectives.</p> <p>23 Q By what objective standard did you apply</p> <p>24 in terms of saying that the authors attributed</p> <p>25 weight to them? Was there some objective scoring</p>

<p style="text-align: right;">Page 190</p> <p>1 system that you used?</p> <p>2 MR. TISI: Objection. Assumes --</p> <p>3 THE WITNESS: I'm sorry, can you --</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q Did you use some objective scoring</p> <p>6 system in defining the weight that was -- that the</p> <p>7 authors attributed to these studies?</p> <p>8 MR. TISI: Objection.</p> <p>9 THE WITNESS: No. In fact, the authors</p> <p>10 in their -- let me back up.</p> <p>11 I assume you're referring to the 2009</p> <p>12 PCPC report?</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q Yes, that's what you're referring to</p> <p>15 there, right?</p> <p>16 MR. TISI: That's why I asked you to</p> <p>17 read her entire sentence.</p> <p>18 Go ahead.</p> <p>19 BY MR. HEGARTY:</p> <p>20 Q Let me go -- let me strike that and let</p> <p>21 me ask a different question.</p> <p>22 Can you cite all of -- what authority do</p> <p>23 you have to say that FDA or any other regulatory</p> <p>24 or policy entity gave importance, added or</p> <p>25 otherwise, to the 2003 or 2007 studies?</p>	<p style="text-align: right;">Page 192</p> <p>1 Q So it's not your testimony that FDA gave</p> <p>2 the 2003 and 2007 articles added importance over</p> <p>3 anything else they reviewed; is that correct?</p> <p>4 A I think I already answered that and said</p> <p>5 we don't know exactly how they weighed these</p> <p>6 articles. I think you're misstating what I --</p> <p>7 what I wrote.</p> <p>8 Q You don't know what -- how FDA weighed</p> <p>9 the 2009 submission either, correct?</p> <p>10 A Correct. Just that they reviewed it.</p> <p>11 Q Is it your claim that it was not within</p> <p>12 PCP's right to submit material to FDA regarding</p> <p>13 the citizen petition?</p> <p>14 A No, not at all.</p> <p>15 Q FDA regulations expressly allow this,</p> <p>16 right?</p> <p>17 A Correct.</p> <p>18 Q Was any group, entity or person</p> <p>19 precluded from submitting materials to FDA?</p> <p>20 A Not that I'm aware of.</p> <p>21 Q Is it your opinion that PCPC should be</p> <p>22 incriminated because no one else chose to file a</p> <p>23 submission?</p> <p>24 A No, not at all.</p> <p>25 Q Is it your testimony that PCPC, J&J or</p>
<p style="text-align: right;">Page 191</p> <p>1 A The -- the basis -- I think I've already</p> <p>2 answered this question. The basis is that the</p> <p>3 data was submitted in response to the citizens</p> <p>4 petition. The FDA clearly cites in their denial</p> <p>5 letter that they considered the data submitted in</p> <p>6 response to the petition. That gives, as the only</p> <p>7 comment submitted in response to the -- to the</p> <p>8 submission and the nature of the report therein,</p> <p>9 added weight and -- and prominence.</p> <p>10 Q Is it your contention that all FDA</p> <p>11 considered was the 2009 submission?</p> <p>12 A No. Again, I've answered that question.</p> <p>13 I -- because of the lack of detail of -- of their</p> <p>14 process and how they weighed the evidence, I can't</p> <p>15 answer specifically what they did and how much</p> <p>16 weight they gave to these studies.</p> <p>17 Q Cite all support from -- that you have</p> <p>18 to say that FDA gave the 2003 and 2007 articles</p> <p>19 added importance over any other materials they</p> <p>20 reviewed.</p> <p>21 A I think you missed -- misstated what was</p> <p>22 in my report. I didn't say FDA gave them.</p> <p>23 Q Okay.</p> <p>24 A You should read back probably what you</p> <p>25 said.</p>	<p style="text-align: right;">Page 193</p> <p>1 Imerys intended to give improper weight to these</p> <p>2 studies to influence FDA?</p> <p>3 A Again, I'm not -- I'm not -- well,</p> <p>4 repeat the question. Sorry.</p> <p>5 Q Is it your opinion -- or strike that.</p> <p>6 Do you intend to testify that PCPC, J&J</p> <p>7 or Imerys intended to give improper weight to</p> <p>8 these studies to influence FDA?</p> <p>9 A No, that's not my opinion. I'm not</p> <p>10 testifying to that.</p> <p>11 Q Is it your opinion that Drs. Huncharek</p> <p>12 and Muscat intended to give improper weight to</p> <p>13 their studies to influence FDA as part of their</p> <p>14 submission in 2009?</p> <p>15 A I'm not opining on intent. I'm opining</p> <p>16 on the facts, and the facts are that they did do</p> <p>17 that. So that's a fact.</p> <p>18 Q You claim in the second paragraph on</p> <p>19 page 9 that the 2003 and 2007 articles were</p> <p>20 advocated to the medical and scientific community.</p> <p>21 How were these articles advocated?</p> <p>22 MR. TISI: Where is that, Counsel?</p> <p>23 MR. HEGARTY: Last line of the second</p> <p>24 paragraph on page 9.</p> <p>25 MR. TISI: You said attribute -- oh,</p>

<p style="text-align: right;">Page 194</p> <p>1 advocated. I see.</p> <p>2 THE WITNESS: Sorry, let me read the</p> <p>3 whole sentence, please.</p> <p>4 (Peruses document.)</p> <p>5 MR. TISI: Could you open the door a</p> <p>6 little bit, Mark. Honestly, it's -- it's really</p> <p>7 hot in here.</p> <p>8 THE WITNESS: Sure, I think -- I think</p> <p>9 this comes back to the -- some previous points</p> <p>10 that we discussed in -- in terms of how the</p> <p>11 authors elevated their own studies within the 2009</p> <p>12 report, how data that was generated in 2000 was</p> <p>13 then repeatedly replicated and disseminated to the</p> <p>14 scientific and medical community over the course</p> <p>15 of almost a decade.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q Who advocated the data from the 2003 and</p> <p>18 2007 studies to the medical and scientific</p> <p>19 community?</p> <p>20 A The authors and whoever funded the</p> <p>21 papers.</p> <p>22 Q Okay. And how were they advocated?</p> <p>23 A By repeating and replicating the same --</p> <p>24 the same data, the same messages over and over</p> <p>25 again.</p>	<p style="text-align: right;">Page 196</p> <p>1 they were doing or going to do based on any of the</p> <p>2 articles you reference in your paper or your</p> <p>3 report?</p> <p>4 A I can't speak to that, no --</p> <p>5 Q Can you cite --</p> <p>6 A -- as I sit here.</p> <p>7 Q Can you cite for me anyone in the</p> <p>8 scientific or medical community who relied in any</p> <p>9 way on the 2003, 2007 or 2011 articles?</p> <p>10 A Again, I would say maybe not as I sit</p> <p>11 here, but certainly that could be done.</p> <p>12 Q You've not done that.</p> <p>13 A No.</p> <p>14 Q Can you cite any medical or scientific</p> <p>15 person or group who ever relied on these articles</p> <p>16 in making any decisions as to talc or talc and</p> <p>17 ovarian cancer?</p> <p>18 A Again, I'm not aware of who has cited or</p> <p>19 reviewed -- you know, the full extent of who has</p> <p>20 cited and reviewed these studies. So I can't</p> <p>21 answer that right now.</p> <p>22 Q Is it your testimony that J&J or Imerys</p> <p>23 advocated these articles to the medical and</p> <p>24 scientific community?</p> <p>25 A To the extent -- I think going back to</p>
<p style="text-align: right;">Page 195</p> <p>1 Q Identify any person from the scientific</p> <p>2 or medical community who read the 2003, the 2007</p> <p>3 or 2011 articles.</p> <p>4 A Myself.</p> <p>5 Q Okay. Anybody else?</p> <p>6 A I -- I'm sure there are.</p> <p>7 Q Well, my question is, can you identify</p> <p>8 for me anybody besides yourself who even read the</p> <p>9 2003, 2007 or 2011 articles you reference in your</p> <p>10 paper?</p> <p>11 A I can't name anyone by name, but we</p> <p>12 could probably get hard data on how often they've</p> <p>13 been read or cited.</p> <p>14 Q Did you do anything in terms of talking</p> <p>15 to scientists or doctors or looking up citations</p> <p>16 to try to determine or support your claim that</p> <p>17 these papers were advocated to the medical or</p> <p>18 scientific community?</p> <p>19 A No, I -- I didn't feel the need to do</p> <p>20 that. Again, I think when this same dose-response</p> <p>21 table shows up three, four times over -- over the</p> <p>22 course of 10 years in multiple publications, I</p> <p>23 would say that's advocating for that data.</p> <p>24 Q Can you cite for me anyone in the</p> <p>25 medical and scientific community who changed what</p>	<p style="text-align: right;">Page 197</p> <p>1 my prior answer, to the extent that the authors</p> <p>2 and whoever funded the work to repeatedly</p> <p>3 disseminate the same data over the course of 10</p> <p>4 years, I would say yes.</p> <p>5 Q Well, who at J&J and Imerys advocated</p> <p>6 these articles to the medical and scientific</p> <p>7 community?</p> <p>8 A I don't know the -- I don't know the</p> <p>9 details of who funded what and specific names of</p> <p>10 people.</p> <p>11 Q Well, what was the method that they</p> <p>12 advocated these articles to the medical and</p> <p>13 scientific community?</p> <p>14 A I think I answered that.</p> <p>15 Q Well, what was the answer?</p> <p>16 A Could we read it back?</p> <p>17 Q Well, let me -- let me -- what was --</p> <p>18 what did Imerys and J&J advocate as to these</p> <p>19 articles to the medical and scientific community?</p> <p>20 A I think you're mischaracterizing. The</p> <p>21 data has been advocated through the various</p> <p>22 publications. So the same data being repeated,</p> <p>23 the same assessment of the data being repeated,</p> <p>24 the same error-prone data being repeated and</p> <p>25 disseminated over the course of 10 years.</p>

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<p style="text-align: right;">Page 198</p> <p>1 Q So who did J&J and Imerys advocate this</p> <p>2 data to?</p> <p>3 A Oh, I can't answer that.</p> <p>4 Q And when did they --</p> <p>5 A Other than --</p> <p>6 Q -- advocate the data?</p> <p>7 A Other than to the extent that</p> <p>8 disseminating findings to the medical and</p> <p>9 scientific community is advocating in the sense</p> <p>10 that you are putting something out there to help</p> <p>11 influence and change decision-making.</p> <p>12 Q Okay. When did they disseminate this --</p> <p>13 these findings to the medical and scientific</p> <p>14 community?</p> <p>15 A Whenever the -- the papers were</p> <p>16 published.</p> <p>17 Q And how did J&J and Imerys go about</p> <p>18 disseminating the medic- -- the findings to the</p> <p>19 medical and scientific community?</p> <p>20 A I -- I think I answered that.</p> <p>21 Q Well, what was the means by which they</p> <p>22 disseminated the findings to the medical and</p> <p>23 scientific community?</p> <p>24 A Through publications.</p> <p>25 Q So you're saying that Imerys and J&J</p>	<p style="text-align: right;">Page 200</p> <p>1 A Number 6.</p> <p>2 Q And you're saying number 6 demonstrates</p> <p>3 that J&J and Imerys were involved in the</p> <p>4 preparation of the 2003 and 2007 reports -- or</p> <p>5 articles?</p> <p>6 A Yes, that's my understanding, that</p> <p>7 the preliminary data was shared. The same</p> <p>8 dose-response data --</p> <p>9 THE REPORTER: I'm sorry. What was</p> <p>10 that?</p> <p>11 THE WITNESS: Preliminary data was</p> <p>12 shared.</p> <p>13 There was a little -- actually a little</p> <p>14 bit that changed between the 2000 and the 2003</p> <p>15 paper, but overall, the dose-response data was</p> <p>16 shared in the 2000 preliminary data. And then</p> <p>17 related to a publication, there was an e-mail from</p> <p>18 Johns Hopkins and others providing feedback on --</p> <p>19 on the paper.</p> <p>20 BY MR. HEGARTY:</p> <p>21 Q The reference you make there was to a</p> <p>22 meta-analysis done to submit to NTP, correct?</p> <p>23 A I don't know specifically what was</p> <p>24 submitted to NTP, but this is my understanding of</p> <p>25 at least demonstrating that there was sharing of</p>
<p style="text-align: right;">Page 199</p> <p>1 published the materials to the medical -- the 2003</p> <p>2 and 2007 articles?</p> <p>3 A That's not what I said. That's not what</p> <p>4 I said.</p> <p>5 What I said was to the extent that</p> <p>6 someone is funding a study or participating in a</p> <p>7 study and then publishing that study, you are</p> <p>8 disseminating that data to the medical and</p> <p>9 scientific community.</p> <p>10 Q Is it your testimony that J&J and Imerys</p> <p>11 published the 2003 and 2007 studies?</p> <p>12 A No, that's not what I said.</p> <p>13 Q Okay. Tell me the involvement that J&J</p> <p>14 and Imerys had in the 2003 and 2007 studies.</p> <p>15 A Well, again --</p> <p>16 Q Besides funding, if any.</p> <p>17 A I have seen e-mails related to some of</p> <p>18 the papers in which employees provided feedback</p> <p>19 related to the papers.</p> <p>20 Q Okay. Where is that written in your</p> <p>21 report?</p> <p>22 A I think there's a footnote actually that</p> <p>23 speaks to that. Let me see.</p> <p>24 (Peruses document.) Page 14.</p> <p>25 Q What footnote?</p>	<p style="text-align: right;">Page 201</p> <p>1 the data and involvement in -- in the data.</p> <p>2 Q So is it your testimony that the</p> <p>3 meta-analysis you reference in footnote 6 was the</p> <p>4 article that was published in 2003?</p> <p>5 A It's certainly parts of this. The data</p> <p>6 from the 2000 preliminary report shows up again in</p> <p>7 the 2003 paper, so they are connected in that way.</p> <p>8 Q So the -- it's your testimony that J&J</p> <p>9 and Imerys published the 2003 paper?</p> <p>10 MR. TISI: Objection.</p> <p>11 THE WITNESS: No, that's not what I</p> <p>12 said.</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q Who published the paper?</p> <p>15 A Well, the authors presumably published</p> <p>16 the paper, but I think if you go back to my prior</p> <p>17 response about funders involved --</p> <p>18 Q Well, what is your definition of</p> <p>19 "advocating"?</p> <p>20 A I also already answered that, but</p> <p>21 I'll -- I'll answer again.</p> <p>22 Anytime someone publishes results and</p> <p>23 puts them out into the medical and scientific</p> <p>24 community, it's to inform policy, program,</p> <p>25 healthcare and public health decision-making. So</p>

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<p>1 you are advocating for that data as part of that</p> <p>2 process.</p> <p>3 MR. HEGARTY: Do you want to -- I'm</p> <p>4 about to go on to another section. You want to</p> <p>5 take the lunch break now or --</p> <p>6 MR. TISI: It's totally -- it's totally</p> <p>7 okay. The lunch is here. I was told --</p> <p>8 MR. HEGARTY: It's up to you.</p> <p>9 MR. TISI: I'm reading it, and it said</p> <p>10 take lunch available at 12:30. So that's what I'm</p> <p>11 assuming, that lunch is available at 12:30.</p> <p>12 MR. HEGARTY: Okay. Why don't -- it's a</p> <p>13 good breaking --</p> <p>14 MR. TISI: I haven't seen anybody walk</p> <p>15 by.</p> <p>16 MR. HEGARTY: It's a good break point if</p> <p>17 you want to do it now because the next section</p> <p>18 will go for a while.</p> <p>19 MR. TISI: I don't care. Okay.</p> <p>20 MR. HEGARTY: You will not be</p> <p>21 disappointed.</p> <p>22 THE VIDEOGRAPHER: Let's go off the</p> <p>23 record. The time is 12:46 p.m. We're going off</p> <p>24 the record.</p> <p>25 (Lunch recess.)</p>	<p>1 THE WITNESS: No. That's correct.</p> <p>2 MR. HEGARTY: Do you have anything else</p> <p>3 you want to add?</p> <p>4 MR. TISI: The only thing I want to add</p> <p>5 is, and I think she clarified it, but you're not</p> <p>6 feeling confident in her ability to go forward</p> <p>7 because you've been very ill since lunch, right?</p> <p>8 THE WITNESS: Yes. And I want to be</p> <p>9 able to do my best.</p> <p>10 MR. HEGARTY: Yes, we want you to do</p> <p>11 your best.</p> <p>12 MR. TISI: So we got about I guess three</p> <p>13 hours and 50 minutes or so, whatever the number</p> <p>14 is --</p> <p>15 THE VIDEOGRAPHER: 3 hours, 52 minutes.</p> <p>16 MR. TISI: -- and we will reschedule it</p> <p>17 at a time we can get this done. And I personally</p> <p>18 apologize.</p> <p>19 THE WITNESS: I apologize as well.</p> <p>20 MR. TISI: We did the best we could.</p> <p>21 This was not my intent.</p> <p>22 MR. HEGARTY: There's no disagreement on</p> <p>23 that.</p> <p>24 THE WITNESS: Nor mine.</p> <p>25 MR. TISI: Not that we're testifying to</p>
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<p>1 MR. HEGARTY: We're back on the record,</p> <p>2 not on the video record, and we've talked with</p> <p>3 counsel and understand that the doctor is not</p> <p>4 feeling well and is not feeling confident in her</p> <p>5 ability to go forward and complete the deposition</p> <p>6 which could go on for the next few hours. So</p> <p>7 we're in agreement to adjourn the deposition to</p> <p>8 another day.</p> <p>9 But I did want to ask you, Doctor, if</p> <p>10 you can, to confirm that with regard to the point</p> <p>11 in time when we took a break for lunch, that you</p> <p>12 felt well enough and that you understood the</p> <p>13 questions that I asked, and that your answers were</p> <p>14 appropriate from your standpoint and not -- they</p> <p>15 weren't influenced by how you are feeling today.</p> <p>16 Would that be a true statement?</p> <p>17 THE WITNESS: Yes. I was able to focus</p> <p>18 and understand your questions this morning. But</p> <p>19 after profuse vomiting, I'm feeling significantly</p> <p>20 worse.</p> <p>21 MR. HEGARTY: I'm sorry to hear that.</p> <p>22 And you were not on any medication such</p> <p>23 that it affected your ability to understand my</p> <p>24 questions or give responses this morning, were</p> <p>25 you?</p>	<p>1 intent or anything like that.</p> <p>2 MR. HEGARTY: That's a good one. Let's</p> <p>3 go off the record.</p> <p>4 (Whereupon, the deposition</p> <p>5 of APRIL ZAMBELLI-WEINER, Ph.D.</p> <p>6 was adjourned at 2:12 p.m.)</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

April Zambelli-Weiner, Ph.D.

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1 CERTIFICATE OF CERTIFIED SHORTHAND REPORTER	1 -----
2 The undersigned Certified Shorthand Reporter	2 E R R A T A
3 does hereby certify:	3 -----
4 That the foregoing proceeding was taken before	4 PAGE LINE CHANGE
5 me at the time and place therein set forth, at	5 _____
6 which time the witness was duly sworn; That the	6 REASON: _____
7 testimony of the witness and all objections made	7 _____
8 at the time of the examination were recorded	8 REASON: _____
9 stenographically by me and were thereafter	9 _____
10 transcribed, said transcript being a true and	10 REASON: _____
11 correct copy of my shorthand notes thereof; That	11 _____
12 the dismantling of the original transcript will	12 REASON: _____
13 void the reporter's certificate.	13 _____
14 In witness thereof, I have subscribed my name	14 REASON: _____
15 this date: January 12, 2019.	15 _____
16	16 REASON: _____
17	17 _____
18 LESLIE A. TODD, CSR, RPR	18 REASON: _____
19 Certificate No. 5129	19 _____
20	20 REASON: _____
21 (The foregoing certification of	21 _____
22 this transcript does not apply to any	22 REASON: _____
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1 INSTRUCTIONS TO WITNESS	1 ACKNOWLEDGMENT OF DEPONENT
2 Please read your deposition over carefully and	2 I, _____, do hereby
3 make any necessary corrections. You should state	3 certify that I have read the foregoing pages, and
4 the reason in the appropriate space on the errata	4 that the same is a correct transcription of the
5 sheet for any corrections that are made.	5 answers given by me to the questions therein
6 After doing so, please sign the errata sheet	6 propounded, except for the corrections or changes
7 and date it.	7 in form or substance, if any, noted in the
8 You are signing same subject to the changes	8 attached Errata Sheet.
9 you have noted on the errata sheet, which will be	9 _____
10 attached to your deposition. It is imperative	10
11 that you return the original errata sheet to the	11 APRIL ZAMBELLI-WEINER, Ph.D. DATE
12 deposing attorney within thirty (30) days of	12
13 receipt of the deposition transcript by you. If	13
14 you fail to do so, the deposition transcript may	14 Subscribed and sworn to
15 be deemed to be accurate and may be used in court.	15 before me this
16	16 _____ day of _____, 20____.
17	17 My commission expires: _____
18	18 _____
19	19 Notary Public
20	20
21	21
22	22
23	23
24	24
25	25